UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

EXELA PHARMA SCIENCES, LLC
1245 Blowing Rock Blvd.
Lenoir, NC 28645

Plaintiff,

v.

DEPARTMENT OF HEALTH
AND HUMAN SERVICES,
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C., 20201

Defendant.

Civil Action

No.1:23-cv-1242

COMPLAINT

INTRODUCTION

1. Plaintiff Exela Pharma Sciences, LLC ("Exela" or "Plaintiff") brings this action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, as amended, challenging the failure of Defendant the Department of Health and Human Services ("HHS" or "Defendant"), to respond to and fulfill Exela's FOIA request for records.

2. Exela submitted three FOIA requests to HHS on March 13, 2023.

3. Exela's first FOIA request seeks documents and records related to the development, drafting, and/or publication of the Food and Drug Administration's ("FDA") interim draft guidance titled *Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations* (the "December 2022 Draft Guidance"), which proposes to substantially increase the amount of aluminum permitted in cysteine hydrochloride injection products ("FOIA Request One"). Ex. 1.

4. Exela's second FOIA request seeks documents and records related to the submission and review of Abbreviated New Drug Application ("ANDA") 213073, ANDA 214082, and ANDA 209994 by HHS. ("FOIA Request Two"). Ex. 12.

5. Exela's third FOIA request seeks documents and records related to HHS's external communications with Congress and other third parties regarding aluminum content in cysteine drug products ("FOIA Request Three"). Ex. 21.

6. Exela accordingly brings this suit to compel HHS to immediately respond to Exela's FOIA requests and promptly disclose all responsive, non-exempt records.

PARTIES

7. Plaintiff Exela is a company existing under the laws of the state of Delaware and authorized to do business in North Carolina, having a principal place of business at 1245 Blowing Rock Blvd., Lenoir, North Carolina 28645. Exela develops, manufactures, and markets sterile injectable pharmaceutical products.

8. Defendant HHS is a federal agency within the meaning of the Freedom of Information Act, 5 U.S.C. § 552(f)(1).

LEGAL STANDARD

9. FOIA requires a federal administrative agency to promptly make available requested, non-exempt agency records in response to a request that (a) reasonably describes such records, and (b) "is made in accordance with published rules stating the time, place, fees, . . . and procedures to be followed." 5 U.S.C. § 552(a)(3)(A); *see also* 45 C.F.R. § 5.21.

10. FOIA requires federal agencies to respond to a valid request within 20 working days (exempting Saturdays, Sundays, and legal public holidays) after receipt of such request,

including notifying the requestor immediately of its determination, the reasons therefore, and the right to appeal any adverse determination. 5 U.S.C. § 552(a)(6)(A)(i); 45 C.F.R. § 5.24.

11. This 20-day time limit may not be tolled by the agency, except (a) that the agency may make one request of the requester for additional information regarding the specifics of the request and toll the 20-day period while it is waiting for that information; or (b) if it is necessary to clarify with the requester issues regarding fee assessment. 5 U.S.C. § 552(a)(6)(A)(ii); 45 C.F.R. § 5.24(c). In either case, the agency's receipt of the requester's response ends the tolling period. *Id.*

12. In "unusual circumstances," FOIA allows the 20-day time limit to be extended 10 days by written notice "setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i); *see also* 45 C.F.R. § 5.24(f).

13. If "unusual circumstances" are invoked, the agency must not only provide written notice as detailed above but must also provide the requester "an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request." 5 U.S.C. § 552(a)(6)(B)(ii); *see also* 45 C.F.R. § 5.24(f).

14. "Unusual circumstances" (as used in the context of FOIA) only occur when, to the extent reasonably necessary to the proper processing of the requester's requests, the agency would need to (1) search for and collect records from another facility separate from the office processing the request; (2) search for, collect, and properly examine a voluminous amount of records demanded in a single request; or (3) consult with another agency to satisfy the request. *See* 5 U.S.C. § 552 (a)(6)(B)(iii).

15. If the federal agency does not respond to a FOIA request by the statutory deadline, the requester is deemed to have exhausted administrative remedies and may immediately pursue judicial review. 5 U.S.C. § 552(a)(6)(C)(i).

JURISDICTION AND VENUE

16. This Court has jurisdiction under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. §§ 1331, 2201.

17. Venue lies with this district under 28 U.S.C. § 1391(e)(1) because an agency of the United States is a Defendant.

FACTS

18. Exela is an award-winning specialty pharmaceutical company that develops, manufactures, and markets high-quality pharmaceutical products, with a particular focus on producing generic sterile injectable products for the U.S. market.

19. One particular pharmaceutical product that Exela has developed, manufactured, and marketed is an L-Cysteine injection product used as a nutritional supplement for preterm newborns and other infants (together, "newborns") and a small number of adults with severe liver disease (together, "high-risk individuals"). Exela's L-Cysteine injection product is called Elcys® and was approved by the FDA on April 16, 2019.

20. Elcys® is a parenteral nutrition ("PN") product that delivers essential nutrients intravenously as part of a nutrition regimen for newborns and high-risk individuals. The therapeutically active ingredient in Elcys® is L-cysteine hydrochloride ("cysteine"), which is an amino acid that is necessary for all humans to mitigate oxidative stress on their bodies and promote the proper absorption of essential nutrients. While healthy adults naturally produce enough

cysteine to meet their needs, newborns and high-risk individuals require daily cysteine infusions as part of a PN regimen.

21. PN products such as Elcys® are critically important to the development and survival of these vulnerable patients. However, these same PN products can be a major source of aluminum toxicity. Unfortunately, it is impossible to manufacture cysteine drug products that are 100 percent free of impurities, including aluminum.

22. Newborns receiving PN treatments are especially at risk from exposure to trace amounts of aluminum because their kidneys are underdeveloped, which means they cannot expel excess aluminum as efficiently as healthy adults can. The adverse effects of too much neonatal aluminum exposure are well documented: decades of research established that just a few days of exposure to excess aluminum in neonatal care can lead to lasting toxicity in the brain, skeletal system, liver, and erythropoietic system. Even fleeting exposure to excess amounts of aluminum can pose grave risks to preterm and other neonates.

23. The FDA is an agency of HHS that regulates clinical investigations of products under its jurisdiction. The FDA previously strictly limited the amount of aluminum that could be present in approved PN products, including cysteine. For example, when the FDA was reviewing Elcys®, it imposed an aluminum concentration limit of 145 micrograms per liter ("mcg/L") in a 5% cysteine solution, *i.e.*, 0.0042 mcg Al/mg cysteine.

24. Exela spent millions of dollars to minimize the amount of aluminum in Elcys® and to satisfy this regulatory requirement. The FDA eventually approved Elcys® with a labeled aluminum content amount of no more than 120 mcg/L (0.0035 mcg Al/mg cysteine).

25. In December 2022, however, the FDA released an interim "Draft Guidance" proposing to substantially increase its recommended aluminum limits for cysteine products. The

FDA's December 2022 Draft Guidance suggests that the FDA could allow cysteine hydrochloride products intended for PN with aluminum content as high as 2500 mcg/L in a 7.25% cysteine hydrochloride product, *i.e.*, 0.0500 mcg Al/mg cysteine, a significantly higher aluminum content limit than the FDA enforced against Exela (after adjusting for the clinically irrelevant cysteine concentration difference between 5.0% and 7.25% cysteine hydrochloride products).

26. On or about January 30, 2023, Exela became aware that the FDA had approved a Nivagen Pharmaceuticals, Inc. ANDA (the "Nivagen ANDA") for another cysteine hydrochloride injection product. Similar to Elcys®, the therapeutically active ingredient in the Nivagen ANDA is L-cysteine. However, unlike the low amounts of aluminum permitted in Elcys®, Nivagen has publicly disclosed that the Nivagen ANDA product is approved to contain up to 3000 mcg/L of aluminum in a 7.25% cysteine hydrochloride solution, which is even higher than the already extraordinary 2500 mcg/L limitation proposed in the December 2022 Draft Guidance.

27. Exela has recently been made aware that the FDA has stayed (but has not revoked or vacated) its approval of Nivagen's ANDA, pending further assessment of its safety by the Agency. Because (1) the Nivagen ANDA remains approved and (2) Exela cannot predict with any certainty how long the Agency may keep in place this stay, the need for the information sought by Exela remains both critical and urgent.

28. Exela submitted three FOIA requests to seek records regarding, *inter alia*, HHS's proposed decision to increase the aluminum content limits applicable to PN products, external communications with third parties regarding that course of action, and any consideration by the agency regarding the December 2022 Draft Guidance's harmful implications for newborns and high-risk individuals.

A. FOIA Request One

29. Exela submitted FOIA Request One on March 13, 2023, requesting records regarding the development, drafting, and/or publication of the December 2022 Draft Guidance, with the requested date range spanning January 1, 2021, through the date of production. Ex. 1. This request expressly included, *inter alia*, records within HHS as well as between HHS and any other Federal or State agencies other than the FDA, Congress, and any non-governmental entities or individuals. *Id.* at 1-2.

30. FOIA Request One included a request that responsive documents be made available as soon as they are located and reviewed via a rolling production. *Id.* at 4.

31. FOIA Request One also included a request for expedited processing. In making that request, Exela argued that the lack of public information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of" newborns. *Id.* at 2-3.

32. After submitting FOIA Request One through the online portal, Exela received a confirmation of submission of FOIA Request One via email on March 14, 2023, along with a reference number, 2023-00558-FOIA-OS. Ex. 2.

33. On March 15, 2023, HHS sent an email to Exela requesting clarification regarding FOIA Request One. Ex. 3. Attached to the email was a letter dated March 15, 2023, in which HHS stated that the records requested were not described "with enough specificity to allow [HHS] to continue with the processing of [Exela's] request." Ex. 4. However, HHS did not request information or clarification regarding the scope or meaning of the requests themselves; instead, HHS requested that Exela provide the "name of HHS employees and name and email domain names of all external individuals who communicate" relating to the subject matter of FOIA

Request One and requested Exela provide key search terms "for an effective and efficient search". *Id.*

34. Exela responded to HHS's "clarification letter" on March 20, 2023. Exs. 5 and 6. In its response, Exela explained that its original request was sufficiently specific under FOIA, and that the regulations HHS relied on in the clarification letter do not require FOIA requesters to identify each (or any) of the particular individuals who may have been involved in creating certain responsive records, or to supply any of the additional information demanded. Ex. 5. Nonetheless, Exela provided to HHS a suggested list of 33 names and email domains for its search along with key search terms that may be responsive to the request, while making clear that it was not limiting the scope of its request in any way. *Id.* Exela indicated that because HHS had provided no basis for refusing to commence a search, HHS's clarification letter was inadequate to toll its 20-day deadline for a response under FOIA. *Id.* at 1, n.1.

35. On March 28, 2023, Exela received an email and acknowledgement letter dated March 28, 2023, confirming that FOIA Request One was received by HHS on March 14, 2023. Exs. 7 and 8.

36. Additionally, in the March 28 letter, HHS invoked "unusual circumstances" stating the records Exela seeks require the agency to search another office. Ex. 7. HHS asserted it would need *more than* the 10 additional days added by the invocation of "unusual circumstances" under FOIA. *Id.* HHS was not clear as to its exact timeline, indicating only that the actual time required to respond to Exela's request would be determined by the complexity and volume of the records search. *Id.* HHS also suggested that Exela may wish to (1) narrow the scope of its request or (2) agree to an alternative time frame for processing. *Id.*

37. On March 28, 2023, Exela received a separate email from HHS indicating that Exela's request was now "In Process." Ex. 9.

38. On April 18, 2023, Exela sent a letter to HHS, in which Exela agreed to limit the scope of its original request. Ex. 10. Accordingly, instead of the original date range of January 1, 2021 through the date of production, Exela proposed a narrowed date range of December 1, 2021, through the date of production. *Id.* To date, HHS has not responded to Exela's proposed narrowing of its request. Exela also inquired regarding its request for expedited processing because HHS had not communicated its determination in response to that request, as required by FOIA. *Id.*

39. On April 20, 2023, HHS denied Exela's request for expedited processing. Ex. 11. HHS stated that Exela had failed to demonstrate a "compelling need." *Id.*

40. Since March 14, 2023, the date HHS acknowledged receipt of Exela's FOIA Request One, 34 working days have passed.

41. Since March 20, 2023, the date Exela responded to HHS's clarification letter, 30 working days have passed.

42. Exela maintains that the time limit imposed by FOIA was not properly tolled by HHS's March 15, 2023 "clarification letter." Regardless, as of May 1, 2023, at the close of business hours, at least 30 working days have passed since HHS received Exela's request. *See* 5 U.S.C. § 552(a)(6)(A)(i).

43. To date, HHS has not (1) made or communicated its determination in response to FOIA Request One, (2) provided any responsive materials, (3) explained that responsive materials have been or will be withheld, (4) communicated any basis for withholding records, or (5) communicated any timeline by which Exela can expect its requests to be processed.

B. FOIA Request Two

44. Exela submitted FOIA Request Two on March 13, 2023, requesting any records relating to ANDA 213073, ANDA 214082, and ANDA 209994, with the requested date range spanning January 1, 2021, through the date of production. Ex. 12. This request expressly included, *inter alia*, all communications within HHS and by or between HHS (including any Office, Division (other than the FDA), or any other administrative unit of the Agency, and/or any HHS employees) regarding the aluminum content of the three subject drug products. *Id.*at 1-2.

45. FOIA Request Two included a request that responsive documents be made available as soon as they are located and reviewed via a rolling production. *Id.* at 4.

46. FOIA Request Two also included a request for expedited processing. In making that request, Exela argued that the lack of public information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of" newborns. *Id.* at 2-3.

47. After submitting FOIA Request Two through the online portal, Exela received a confirmation of submission of FOIA Request Two via email on March 14, 2023, along with a reference number, 2023-00557-FOIA-OS. Ex. 13

48. On March 15, 2023, HHS sent an email to Exela requesting clarification regarding FOIA Request Two.[1] Ex. 14. Attached to the email was a letter dated March 15, 2023, in which HHS stated that the records requested were not described "with enough specificity to allow [HHS] to continue with the processing of [Exela's] request." Ex. 15. However, HHS did not request information or clarification regarding the scope or meaning of the requests themselves; instead,

[1] The attachment mistakenly referenced another FOIA request. *See* Ex. 14. Exela informed HHS of the mistake, and HHS sent another letter on March 17, 2023, containing the same substantive information.

HHS requested that Exela provide the "name of HHS employees and name and email domain names of all external individuals who communicate" relating to the subject matter of FOIA Request Two and requested Exela provide key search terms "for an effective and efficient search". *Id.*

49. Exela responded to HHS's "clarification letter" on March 20, 2023. Exs. 16 and 6. In its response, Exela explained that its original request was sufficiently specific under FOIA, and that the regulations HHS relied on in the clarification letter do not require FOIA requesters to identify each (or any) of the particular individuals who may have been involved in creating certain responsive records, or to supply any of the additional information demanded. Ex. 16. Nonetheless, Exela provided to HHS a suggested list of 33 names and email domains for its search along with key search terms that may be responsive to the request, while making clear that it was not limiting the scope of its request in any way. *Id.* Exela indicated that because HHS had provided no basis for refusing to commence a search, HHS's clarification letter was inadequate to toll its 20-day deadline for a response under FOIA. *Id.* at 1, n.1.

50. On March 28, 2023, Exela received an email and acknowledgement letter dated March 28, 2023, confirming that FOIA Request Two was received by HHS on March 14, 2023. Exs. 17 and 18.

51. Additionally, in the March 28 letter, HHS invoked "unusual circumstances," stating the records Exela seeks require the agency to search another office. Ex. 17. HHS asserted it would need *more than* the 10 additional days added by the invocation of "unusual circumstances" under FOIA. *Id.* HHS was not clear as to its exact timeline, indicating only that the actual time required to respond to Exela's request would be determined by the complexity and volume of the records

search. *Id.* HHS also suggested that Exela may wish to (1) narrow the scope of its request or (2) agree to an alternative time frame for processing. *Id.*

52. On April 18, 2023, Exela sent a letter to HHS, in which Exela agreed to limit the scope of its original request, including narrowing the scope of the request for each of the three referenced ANDAs and narrowing the date range for each of the three referenced ANDAs. Ex. 19. To date, HHS has not responded to Exela's proposed narrowing of its request. Exela also inquired regarding its request for expedited processing because HHS had not communicated its determination in response to that request, as required by FOIA. *Id.*

53. On April 20, 2023, HHS denied Exela's request for expedited processing. Ex. 20. HHS stated that Exela had failed to demonstrate a "compelling need." *Id.*

54. Since March 14, 2023, the date HHS acknowledged receipt of Exela's FOIA Request Two, 34 working days have passed.

55. Since March 20, 2023, the date Exela responded to HHS's clarification letter, 30 working days have passed.

56. Exela maintains that the time limit imposed by FOIA was not properly tolled by HHS's March 15, 2023 "clarification letter." Regardless, as of May 1, 2023, at the close of business hours, at least 30 working days have passed since HHS received Exela's request. *See* 5 U.S.C. § 552(a)(6)(A)(i).

57. To date, HHS has not (1) made or communicated its determination in response to FOIA Request Two, (2) provided any responsive materials, (3) explained that responsive materials have been or will be withheld, (4) communicated any basis for withholding records, or (5) communicated any timeline by which Exela can expect its requests to be processed.

C. FOIA Request Three

58. Exela submitted FOIA Request Three on March 13, 2023, requesting all records containing or reflecting communication between HHS and Congress and other third parties regarding aluminum content in cysteine drug products, with the requested date range spanning January 1, 2021, through the date of production. Ex. 21.

59. FOIA Request Three included a request that responsive documents be made available as soon as they are located and reviewed via a rolling production. *Id.* at 4.

60. FOIA Request Three also included a request for expedited processing. In making that request, Exela argued that the lack of public information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of" newborns. *Id.* at 2-3.

61. After submitting FOIA Request Three through the online portal, Exela received a confirmation of submission of FOIA Request Three via email on March 13, 2023, along with a reference number, 2023-00555-FOIA-OS. Ex. 22.

62. On March 14, 2023, HHS sent an email to Exela requesting clarification regarding FOIA Request Three. Ex. 23. Attached to the email was a letter dated March 15, 2023, in which HHS stated that the records requested were not described "with enough specificity to allow [HHS] to continue with the processing of [Exela's] request. Ex. 24. However, HHS did not request information or clarification regarding the scope or meaning of the requests themselves; instead, HHS requested that Exela provide the "name of HHS employees and name and email domain names of all external individuals who communicate" relating to the subject matter of FOIA Request Three and requested Exela provide key search terms "for an effective and efficient search". *Id.*

63. Exela responded to HHS's "clarification letter" on March 20, 2023. Exs. 25 and 6. In its response Exela explained that its original request was sufficiently specific under FOIA, and that the regulations HHS relied on in the clarification letter do not require FOIA requesters to identify each (or any) of the particular individuals who may have been involved in creating certain responsive records, or to supply any of the additional information demanded. Ex. 25 Nonetheless, Exela provided to HHS a suggested list of 33 names and email domains for its search along with key search terms that may be responsive to the request, while making clear that it was not limiting the scope of its request in any way. *Id.* Exela indicated that because HHS had provided no basis for refusing to commence a search, HHS's clarification letter was inadequate to toll its 20-day deadline for a response under FOIA. *Id.* at 1, n.1.

64. On March 28, 2023, Exela received an email and acknowledgement letter dated March 28, 2023, confirming that FOIA Request Three was received by HHS on March 14, 2023. Exs. 26 and 27.

65. Additionally, in the March 28 letter, HHS invoked "unusual circumstances" stating the records Exela seeks require the agency to search another office. Ex. 26. HHS asserted it would need *more than* the 10 additional days in addition to the 10 days already added by the invocation of "unusual circumstances" under FOIA. *Id.* HHS was not clear as to its exact timeline, indicating only that the actual time required to respond to Exela's request would be determined by the complexity and volume of the records search. *Id.* HHS also suggested that Exela may wish to (1) narrow the scope of its request or (2) agree to an alternative time frame for processing. *Id.*

66. On March 28, 2023, Exela received a separate email from HHS indicating that Exela's request was now "In Process." Ex. 28.

67. On April 18, 2023, Exela sent a letter to HHS, in which Exela agreed to limit the scope of its original request. Ex. 29. Accordingly, instead of the original date range of January 1, 2021, through the date of production, Exela proposed a narrowed date range of December 1, 2021, through the date of production. *Id.* To date, HHS has not responded to Exela's proposed narrowing of its request. Exela also inquired regarding its request for expedited processing because HHS had not communicated its determination in response to that request, as required by FOIA. *Id.*

68. On April 20, 2023, HHS denied Exela's request for expedited processing. Ex. 30. HHS stated that Exela had failed to demonstrate a "compelling need." *Id.*

69. Since March 13, 2023, the date HHS acknowledged receipt of Exela's FOIA Request One, 35 working days have passed.

70. Since March 20, 2023, the date Exela responded to HHS's clarification letter, 30 working days have passed.

71. Exela maintains that the time limit imposed by FOIA was not properly tolled by HHS's March 14, 2023 "clarification letter." Regardless, as of May 1, 2023, at the close of business hours, at least 30 working days had passed since HHS received Exela's request. *See* 5 U.S.C. § 552(a)(6)(A)(i).

72. To date, HHS has not (1) made or communicated its determination in response to FOIA Request One, (2) provided any responsive materials, (3) explained that responsive materials have been or will be withheld, (4) communicated any basis for withholding records, or (5) communicated any timeline by which Exela can expect its requests to be processed.

FIRST CLAIM FOR RELIEF[2]
(Failure to Comply with Statutory Deadlines in Violation of FOIA)

73. Plaintiff repeats, re-alleges, and reincorporates the allegations in the foregoing paragraphs as though fully set forth herein.

74. FOIA requires HHS to provide a final determination within 20 working days after the receipt of Exela's FOIA request. 5 U.S.C. § 552(a)(6)(A). This 20-day time limit may be extended an additional 10 working days in the event of "unusual circumstances." 5 U.S.C. § 552(a)(6)(B)(i); *see also* 45 C.F.R. § 5.24(f).

75. More than 30 working days have passed since Exela's three FOIA requests were received and logged by HHS. *See* Exs. 1, 12, and 21.

76. To date, HHS has not provided a final determination in response to Exela's FOIA requests, nor has it communicated when Exela can expect its requests to be processed.

77. Additionally, to date, HHS has not responded to Exela's April 18, 2023, proposed narrowing of its request, *See* Exs. 10, 19, and 29.

78. HHS has failed to make a timely determination in response to Exela's FOIA requests, in violation of FOIA. *See* 5 U.S.C. § 552(a)(6).

79. All administrative remedies required by FOIA have been constructively exhausted. *See* 5 U.S.C. § 552(a)(6)(C)(i).

SECOND CLAIM FOR RELIEF
(Unlawful Withholding of Agency Records in Violation of FOIA)

80. The allegations in the foregoing paragraphs are expressly incorporated herein as if restated in full.

[2] Each claim for relief brought by Exela in this complaint applies to all three FOIA requests detailed above.

81. FOIA requires HHS to process records requests and promptly provide the requested records or the reasonably segregable portion of records not subject to a FOIA exemption. 5 U.S.C. § 552(a)(3)(A).

82. To date, HHS has neither provided nor made available any responsive documents in response to Exela's FOIA requests, nor has HHS claimed that any responsive records are exempt from disclosure.

83. Therefore, HHS's failure to promptly produce requested records or claim applicable exemptions violates FOIA. 5 U.S.C. § 552(a)(3)(A).

THIRD CLAIM FOR RELIEF
(Declaratory Judgment)

84. The allegations in the foregoing paragraphs are expressly incorporated herein as if restated in full.

85. For the same reasons described in each of the previous counts, Exela is entitled to a declaratory judgment that HHS has been and is violating the law.

PRAYER FOR RELIEF

Plaintiff respectfully requests that the Court:

A. Declare that HHS failed to make and communicate a timely determination regarding each of Exela's three requests, in violation of FOIA, 5 U.S.C. §§ 552(a)(6)(A)(i), (a)(6)(E)(iii);

B. Declare that HHS failed to promptly provide records responsive to each of Exela's three requests, in violation of FOIA, 5 U.S.C. § 552(a)(3);

C. Order HHS to immediately conduct a reasonable search for all responsive records and demonstrate that it employed search methods reasonably calculated to uncover all records responsive to the requests as required by FOIA, 5 U.S.C. § 552(a)(3)(C);

D. Order HHS to immediately provide a determination on Exela's requests as required by FOIA, 5 U.S.C. § 552(a)(6)(A)(i), and produce a *Vaughn* index of any responsive records withheld under claim of exemption, *see Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 145–46 (D.C. Cir. 2006);

E. Order HHS to promptly make available to Exela all responsive, non-exempt records, as required by FOIA, 5 U.S.C. § 552(a)(3);

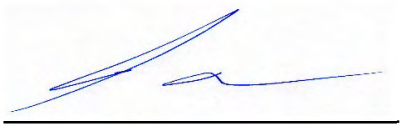
F. Maintain jurisdiction over this action to ensure that HHS produces all non-exempt responsive records to Exela, and that any non-exempt portions of responsive records are not improperly withheld;

G. Award reasonable attorneys' fees and allowable costs, including under 5 U.S.C. § 552(a)(4)(E); and

H. Grant Exela such other and further relief to which it is justly entitled at law and in equity.

Dated: May 2, 2023

Respectfully submitted,



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Counsel for Plaintiff

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS

EXELA PHARMA SCIENCES, LLC

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Caldwell, NC
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

DEPARTMENT OF HEALTH
AND HUMAN SERVICES

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Holtzman Vogel Baran Torchinsky & Josefiak PLLC
2300 N Street NW, Ste. 643A, Washington DC
(202) 737-8808

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A. *Antitrust***

- ☐ 410 Antitrust

○ **B. *Personal Injury/ Malpractice***

- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

○ **C. *Administrative Agency Review***

- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ **D. *Temporary Restraining Order/Preliminary Injunction***

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ **E. *General Civil (Other)*** OR ○ **F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ G. *Habeas Corpus/ 2255* ☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	○ H. *Employment Discrimination* ☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	◉ I. *FOIA/Privacy Act* ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ J. *Student Loan* ☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ K. *Labor/ERISA (non-employment)* ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ L. *Other Civil Rights (non-employment)* ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	○ M. *Contract* ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ N. *Three-Judge Court* ☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
Plaintiff brings this action under the Freedom of Information Act, 5 U.S.C. § 552, as amended, challenging the failure of Defendant the Department of Health and Human Services ("HHS") to timely respond to Plaintiff's request for records

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F R C P 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint YES ☐ NO ☒

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☐ NO ☒ If yes, please complete related case form

DATE: 05/02/2023 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Jason Torchinsky

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

FOIA Summons
1/13

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

EXELA PHARMA SCIENCES, LLC
Plaintiff

v.

DEPARTMENT OF HEALTH AND HUMAN SERV
Defendant

Civil Action No. 1:23-cv-1242

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

United States Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jason Torchinsky, Esq.
Holtzman Vogel Baran Torchinsky
& Josefiak PLLC
2300 N Street, NW
Suite 643A
Washington, DC 20037

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

EXELA PHARMA SCIENCES, LLC
Plaintiff

v.

DEPARTMENT OF HEALTH AND HUMAN SERV
Defendant

Civil Action No. 1:23-cv-1242

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

U.S. Department of Justice
Attn: Merrick B. Garland
Attorney General of the United States
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jason Torchinsky, Esq.
Holtzman Vogel Baran Torchinsky
& Josefiak PLLC
2300 N Street, NW
Suite 643A
Washington, DC 20037

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

FOIA Summons
1/13

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

EXELA PHARMA SCIENCES, LLC
Plaintiff

v.

DEPARTMENT OF HEALTH AND HUMAN SERV
Defendant

Civil Action No. 1:23-cv-1242

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

U.S. Attorney's Office for D.C.
Attn: Civil Process Clerk
601 D Street, NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jason Torchinsky
Holtzman Vogel Baran Torchinsky
& Josefiak PLLC
2300 N Street, NW
Suite 643A
Washington, DC 20037

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

EXHIBIT 1

EXELA
PHARMA SCIENCES
1245 Blowing Rock Blvd
Lenoir, NC 28645
www.exelapharma.com

March 13, 2023

Arianne Perkins
Freedom of Information Officer
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Freedom of Information Act (FOIA) Request

Dear Freedom of Information Officer:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and HHS's FOIA implementing regulations, 45 C.F.R. § 5.21 *et seq*., Phanesh Koneru, Bridget Archer, and Exela Pharma Sciences, LLC (collectively "Requesters") hereby request the following records[1] in HHS's possession on or after January 1, 2021 through the date of production:

> All records relating to development, drafting, and/or publication of the December 2022 Draft Guidance titled *Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations* (the "December Guidance"), including all records received, reviewed, or considered by HHS (including any Office, Division (other than the U.S. Food and Drug Administration ("FDA"[2]), or other administrative unit of the Department, and/or any HHS employees), to the extent they exist, relating to the December Guidance. Please be sure to include all memoranda, briefings, meeting minutes, reports, notes, talking points, opinions, directives, policy statements, and any other records reflecting or memorializing communications relating to the December Guidance both (1) within HHS, including, but not limited to, communications by, within, between, or among HHS's Office of the General

[1] "Records," as that term is defined under FOIA (5 U.S.C. § 552(f)(2)), and under applicable case law (*see, e.g.*, *Forsham v. Harris*, 445 U.S. 169, 193 (1980)) include, but are not limited to, written correspondence, memoranda, records kept in electronic format on computers and/or electronic storage devices, email correspondence (whether through .gov email addresses or private third-party services such as Gmail), records of telephone correspondence, records pertaining to in-person meetings, calendar or scheduling entries, videotapes, photographs, computer print-outs, telephone messages, or voicemail messages.

[2] Requesters have filed separate FOIA requests directly with FDA and therefore do not need HHS to search FDA's records for responsive documents.

> Counsel, Office of the Assistant Secretary for Health, and/or the Immediate Office of the Secretary; and (2) between or among HHS and any other Federal or State departments or agencies (other than FDA) or their administrative units or employees; Congress (including Members of Congress, committees, subcommittees, and/or congressional staff); and any non-governmental corporations, companies, partnerships, unincorporated associations, or other entities or individuals.

Because of the time-sensitive nature of this request, Requesters ask that you strictly comply with FOIA's 20-day deadline. *See* 5 U.S.C. § 552(a)(6)(A). Along with our outside counsel, Requesters would be pleased to discuss this request with you if doing so could help facilitate a timely response. Finally, Requesters ask that HHS process this request consistent with the Department of Justice's policy memorandum (directed to the heads of executive departments and agencies) emphasizing the presumption of disclosure under FOIA, as amended by the FOIA Improvement Act of 2016.[3]

Request for Expedited Processing: Requesters further request that HHS provide expedited processing of this FOIA request. This request qualifies for expedited treatment pursuant to 45 C.F.R. § 5.27(b)(1) and 5 U.S.C. § 552(a)(6)(E) because the lack of publicly available information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of an individual," 5 U.S.C. § 552(a)(6)(E)(v)(I), including many preterm infants—whose lives depend on using these products, but who may be seriously harmed by exposure to unsafe levels of aluminum contamination in the process.[4]

L-cysteine is a necessity for proper human life functioning. While healthy adults can naturally synthesize small amounts of L-cysteine, certain high-risk patients—including preterm and/or low birth weight infants and patients with severe liver disease—require L-cysteine supplementation by parenteral administration. Aluminum toxicity in the administration of such treatment can cause serious health problems, including bone toxicity, dementia, impaired neurologic development, Alzheimer's disease, and liver disease, among other conditions. Federal regulation of aluminum in these products thus has a direct impact on the health and safety of society's most vulnerable individuals, and the lack of publicly available information concerning aluminum levels in cysteine products "could reasonably be expected to pose an imminent threat to the life or physical safety," *id.*; 45 C.F.R. § 5.27(b)(1), by depriving healthcare professionals of critical information needed to ensure the health and safety of highly vulnerable patients, including preterm infants who require total parenteral nutrition ("TPN") and adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. Patients with underlying renal impairment who receive prolonged courses of parenteral nutrition support are at greatest risk of

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[3] Dep't of Justice Office of Information Policy, Memorandum from The Attorney General, March 15, 2022, *available at* https://www.justice.gov/ag/page/file/1483516/download (last visited September 10, 2022).

[4] *See, e.g.*, Mark R. Corkins, "Review finds greatest risk of aluminum exposure is via parenteral nutrition," American Academy of Pediatrics News, Nov. 25, 2019, *available at* https://publications.aap.org/aapnews/news/13404 (last visited Mar. 6, 2023); Mark R. Corkins, Praveen S. Goday, and Ellen S. Rome, "Aluminum Effects in Infants and Children," American Academy of Pediatrics, vol. 144, no. 6 (Dec. 2019), *available at* https://publications.aap.org/pediatrics/article/144/6/e20193148/37901/Aluminum-Effects-in-Infants-and-Children?autologincheck=redirected (last visited Mar. 6, 2023); Heather A. Wier and Robert J. Kuhn, "Aluminum Toxicity in Neonatal Parenteral Nutrition: What Can We do?" SAGE Journals, vol 45, no. 1 (Jan. 2012), *available at* https://journals.sagepub.com/doi/10.1345/aph.1Q399 (last visited Mar. 6, 2023).

exposure to toxic levels of aluminum from parenteral nutrition. Obtaining the requested records regarding these government activities is necessary to protect the health of these vulnerable individuals.

As required by statute and federal regulation, the undersigned certify that the above information is true and correct to the best of their knowledge and belief.

Search and Processing of Requested Records: Upon receipt of this request, please take all reasonable steps to preserve relevant public records while the request is pending. Please also contact us promptly to provide an estimated date on which you will finish processing this request. Notice is hereby given that the Requesters request an estimation of appropriate fees incurred and assessed for the "document search and duplication" of the department records responsive to this request if such fees should exceed $250.00. 5 U.S.C. § 552(a)(4)(A)(ii)(III).

Please search for responsive records regardless of format, medium, or physical characteristics. Requesters ask that responsive electronic records be produced electronically in their native file format, if possible, or the format most felicitous to an expedited production. Alternatively, Requesters request that the Records be provided electronically in text-searchable PDF, in the best image quality in HHS's possession, and in separate, Bates-stamped files.

If this FOIA request is denied in whole or in part, please provide the reasons for the denial, pursuant to 5 U.S.C. § 552(a)(6)(A)(i). If it is your position that any portion of the requested records is exempt from disclosure, we request that you provide a *Vaughn* index of those documents. *See Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973). As you are aware, a *Vaughn* index must describe each document claimed as exempt with sufficient specificity "to permit a reasoned judgment as to whether the material is actually exempt under FOIA." *Founding Church of Scientology v. Bell*, 603 F.2d 945, 959 (D.C. Cir. 1979). Moreover, the *Vaughn* index must "describe each document or portion thereof withheld, and for each withholding it must discuss the consequences of supplying the sought- after information." *King v. U.S. Dep't of Justice*, 830 F.2d 210, 223–24 (D.C. Cir. 1987).

In the event that some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable, non-exempt portions of the requested records. *See* 5 U.S.C. § 552(b). Pursuant to regulation, please clearly delineate any and all redactions in such a manner so that the justification for each redaction is apparent. If it is your position that a document contains non-exempt segments and that those non-exempt segments are so dispersed throughout the documents as to make segregation impossible, please state what portion of the document is non-exempt, and how the material is dispersed through the document. *Mead Data Cent. v. U.S. Dep't of the Air Force*, 455 F.2d 242, 261 (D.C. Cir. 1977). Claims of non-segregability must be made with the same detail as required for claims of exemptions in a *Vaughn* index. If a request is denied in whole, please state specifically that it is not reasonable to segregate portions of the record for release.

For records available in electronic format, please email the documents to jtorchinsky@holtzmanvogel.com. Please send all other requested documents to the attention of:

Holtzman Vogel Baran Torchinsky & Josefiak

Attn: Jason Torchinsky
2300 N. St. NW Ste. 643A
Washington, D.C. 20037

Finally, we reiterate our request that responsive documents be made available as soon as they are located and reviewed *via* a rolling production. Requesters will pay reasonable increased costs incurred to facilitate a rolling production.

If you have any questions about this request, please do not hesitate to contact either me or my counsel.

Phanesh Koneru
Digitally signed by Phanesh Koneru
Date: 2023.03.13 12:02:45 -04'00'

Phanesh Koneru
Chief Executive Officer
(703) 964-7884
pkoneru@exela.us

Bridget Archer 3-13-2023

Bridget Archer
Pharmacist-in-Charge
(704) 301-7687
barcher@exela.us

EXHIBIT 2

From: noreply@ains.com
Date: March 14, 2023 at 2:37:57 PM GMT+1
To: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>
Subject: Request Acknowledgement by U.S. Department of Health & Human Services

You don't often get email from noreply@ains.com. Learn why this is important

Dear Phanesh Koneru,

Your request has been received by the U.S. Department of Health & Human Services. The request has been assigned tracking # 2023-00558-FOIA-OS, please log into your account and review your submission.

The
application address is https://requests.publiclink.hhs.gov.

Thank you,
U.S. Department of Health & Human Services

EXHIBIT 3

Subject: FW: HHS FOIA Clarification Letter -- 2023-00558-FOIA-OS
Attachments: HHS FOIA 3 -- Guidance -- Related Documents.pdf; Clarification Letter.pdf

From: Noussoukpoe, Ray <foiarequest@hhs.gov>
Sent: Wednesday, March 15, 2023 4:22 PM
To: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>
Subject: HHS FOIA Clarification Letter -- 2023-00558-FOIA-OS

Hello, Phanesh Koneru

Attached is a Clarification Letter to your FOIA request 2023-00558-FOIA-OS. If you have any questions, please contact HHS FOIA Office at FoiaRequest@hhs.gov.

Thank You

EXHIBIT 4

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00558-FOIA-OS

March 15, 2023

Sent via email:
Phanesh Koneru
Exela Pharma Sciences, LLC
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This clarification letter is in response to your March 14, 2023, Freedom of Information Act (FOIA) request. Specifically, you requested the following:

> ***"All records relating to development, drafting, and/or publication of the December Draft Guidance titled Small volume parenteral drug products and pharmacy bulk packages for parenteral nutrition: Aluminum content and labeling recommendations ... (Date Range for Record Search: From 1/1/2021 To 3/14/2023)".***

The FOIA allows the public to request access to "reasonably described" existing agency records (subject to any applicable FOIA exemptions to disclosure). This means you must describe the category of records you are seeking or the actual document(s), and provide sufficient details to permit a search with reasonable effort, utilizing existing indices and search tools.

In accordance with Title 45 Code of Federal Regulations Subtitle A, Subpart B – How to Request Records under FOIA, HHS outlined what must be contained in FOIA requests to allow staff to locate requested records with a reasonable amount of effort. As set out in HHS FOIA Regulations,

> "….. a written description of the records you seek in sufficient detail to enable our staff to locate them with a reasonable amount of effort. The more information you provide, the better possibility we have of finding the records you are seeking. Information that will help us find the records would include:
>
> (1) The agencies, offices, or individuals involved;
> (2) The approximate date(s) when the records were created;
> (3) The subject, title, or description of the records sought; and
> (4) Author, recipient, case number, file designation, or other reference number, if available."

This letter is to obtain clarification regarding your FOIA request.
Unfortunately, you have not described the records with enough specificity to allow us to continue with the processing of your request. As stated in line one (1) name of all HHS employees involved and any other individuals (**external to HHS if any**) involved name and

email domain names are required.
In other words, **name of HHS employees and name and email domain names of all external individuals** who communicate "relating to development, drafting, and/or publication of the December Draft Guidance" are needed to conduct an electronic search for records.

Additionally, provide search key "terms" or "words" to use for an effective and efficient search.

The Office of the Chief Information Officer reports due to technology constraints, HHS cannot run a blind search against all users in HHS or an operating/staff division. Electronic searches run against our live email system and a search against all HHS employees would crash our system.

Regarding the search terms, we would need the domain names for each entity in the list so that we could identify emails to or from a custodian to those entities. For example, “emails to or from Jane Doe (Jane.Doe@hhs.gov) and @organization.org or @commercial_entity.com” with specific key words and date ranges.

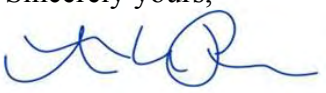
Once you provide the above information/details clarifying you request, we can conduct a search.

At this time, we have placed your request in “tolled” status. Therefore, please clarify and describe the records you are seeking, by sending an email to Ray Noussoukpoe, of my staff, at FOIARequest@hhs.gov.

After you further advise us what records you are seeking, we can begin to process your FOIA request.

HHS “may deny your request for other reasons, including that a request does not reasonably describe the records sought” in accordance with the HHS FOIA Regulations cited in paragraph three. If you have not contacted our office within 30 business days from the date of this letter, your request will be administratively closed. Therefore, no action on your part is needed, if you no longer have a need for the records.

Sincerely yours,



Arianne Perkins
Director
FOI/Privacy Acts Division

EXHIBIT 5

EXELA PHARMA SCIENCES
1245 Blowing Rock Blvd
Lenoir, NC 28645
www.exelapharma.com

March 19, 2023

Arianne Perkins
Freedom of Information Officer
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Case No. 2023-00558-FOIA-OS

Ms. Perkins:

I write in response to your March 15, 2023 letter (the "Clarification Letter") requesting additional information with respect to the above-captioned FOIA request (the "Request"). As you know, that Request sought:

> All records relating to development, drafting, and/or publication of the December 2022 Draft Guidance titled Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations (the "December Guidance"), including all records received, reviewed, or considered by HHS (including any Office, Division (other than the U.S. Food and Drug Administration ("FDA"), or other administrative unit of the Department, and/or any HHS employees), to the extent they exist, relating to the December Guidance. Please be sure to include all memoranda, briefings, meeting minutes, reports, notes, talking points, opinions, directives, policy statements, and any other records reflecting or memorializing communications relating to the December Guidance both (1) within HHS, including, but not limited to, communications by, within, between, or among HHS's Office of the General Counsel, Office of the Assistant Secretary for Health, and/or the Immediate Office of the Secretary; and (2) between or among HHS and any other Federal or State departments or agencies (other than FDA) or their administrative units or employees; Congress (including Members of Congress, committees, subcommittees, and/or congressional staff); and any non-governmental corporations, companies, partnerships, unincorporated associations, or other entities or individuals.

Request at 1 & n.1.

Despite the specificity of our Request—which, generally speaking, seeks all records regarding internal communications within HHS or external communications between HHS and any other Federal or State department or agencies, Congress, or non-governmental entities regarding the December Guidance—the Clarification Letter asserts that the Request did "not describe[] the records with enough specificity" simply because it did not provide the "name of all HHS employees involved and any other individuals (**external to HHS if any**) involved name and email domains are required." Clarification Ltr. at 1-2 (all emphases as in original). The Clarification Letter further suggests that HHS's FOIA regulations ***require*** us to provide this information as a condition of processing the Request. *Id.* at 1 ("In accordance with Title 45 Code of Federal Regulations Subtitle A, Subpart B – How to Request Records under FOIA, HHS outlined what must be contained in FOIA requests to allow staff to locate requested records with a reasonable amount of effort.").

Those assertions are incorrect: The cited regulation does not remotely require FOIA requesters to identify each (or any) of the particular individuals who may have been involved in creating certain responsive records (whether as an author or recipient) or to supply any of the additional information you have demanded.[1] Instead, the cited regulation merely identifies certain kinds of "[i]nformation ***that will help us*** find the records you are seeking" and then lists as, illustrative examples, "the agencies, offices, ***or*** individuals involved" and the "author, recipient, case number, file designation, or other reference number, ***if available***." 45 C.F.R. § 5.22(a)(1), (4) (both emphases added). The Clarification Letter's assertion that this regulation somehow "require[s]" Requesters to provide the information you have demanded therefore is triply flawed.

First, the courts have held that substantially similar FOIA regulations—which merely identify useful categories of information that would be helpful to the processing federal agency—do ***not*** in fact require FOIA requesters to supply all (or indeed any) such information as a condition of processing a FOIA request. *See, e.g.*, *Biear v. Attorney General of the United States*, 905 F.3d 151, 156 (3d Cir. 2018) ("The government contends that Biear's request was insufficiently detailed, in part because it failed to suggest specific sections [of the Department of Justice] in which responsive records might be maintained. The text of the regulation does not require that a request contain that information. It states only that a request should contain that information '[t]o the extent possible.'") (discussing 28 C.F.R. § 16.3(b) ("Requesters must describe the records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount of effort. To the extent possible, requesters should include specific information that may assist a component in identifying the requested records, such as the date, title or name, author, recipient, subject matter of the record, case number, file designation, or reference number.")). HHS's regulation does not differ materially from the Department of Justice's: Just like DOJ's regulation,

[1] We note that the only concerns your response articulates relate to email searches. Clarification Letter at 2 (demanding that Requesters provide "email domain names"); *id.* (complaining that "HHS cannot run a blind search against all users in HHS or an operating/staff division" because "our live email system … would crash"); *id.* (seeking domain name information "so that we could identify emails to or from a custodian to those entities"). But the Request is not limited to emails; it seeks "***All records*** containing or reflecting communications" between HHS and outside parties regarding the specified subject matter, Request at 1 (emphasis added)—some of which may be contained in emails, and some of which may be contained in other Department records. *Id.* at 1 n.1 (defining the term "records"). You therefore have provided no basis for refusing to commence a search of your other systems for responsive records, and Requesters accordingly reject the Clarification Letter's assertion that the deadline for responding to this Request has been, or legitimately can be, "tolled." *Cf.* Clarification Letter at 2.

HHS's regulation begins by asserting that FOIA requesters must describe "the records you seek in sufficient detail to enable our staff to locate them with a reasonable amount of effort," and then identifies certain categories of "information that will help us … if available." 45 C.F.R. § 5.22(a). It does not, however, ***require*** FOIA requesters to supply any such information (whether available or not) as a condition of fulfilling the request, just as the courts have made clear that DOJ's substantially similar regulation includes no such requirement. *See Biear*, 905 F.3d at 156.

Second, the Request fully complied with your regulation in any event. Whether or not the regulation requires Requesters to supply certain categories of information (and it doesn't, for the reasons we have just explained), the Request did exactly what the regulation expressly authorizes: It specifically identified "the agencies, offices, ***or*** individuals involved," 45 C.F.R. § 5.22(a) (emphasis added), by identifying several of the offices in which responsive records likely would be found, including "HHS's Office of the General Counsel, Office of the Assistant Secretary for Health, and/or the Immediate Office of the Secretary." Request at 1. Needless to say, each of the identified "Office[s]" is an "office" within the meaning of 45 C.F.R. § 5.22(a). And the regulation's disjunctive use of the word "***or***" makes clear that FOIA requesters are ***not*** required to supply the names of all "agencies, offices, ***and*** individuals involved" (assuming, for the sake of argument, that it requires anything at all). Any one of those alternatives suffices, and the Request supplied them. *See, e.g.*, *In re Espy*, 80 F.3d 501, 505 (D.C. Cir. 1996) ("[A] statute written in the disjunctive is generally construed as setting out separate and distinct alternatives."); *cf. Loving v. IRS*, 742 F.3d 1013, 1019 (D.C. Cir. 2014) ("[T]he statute uses the conjunctive 'and' — not the disjunctive 'or' — when listing the various requirements, a strong indication that Congress did not intend the requirements as alternatives.").

Finally, the cited regulation expressly acknowledges that FOIA requesters may not have the information you are demanding Requesters now provide—here, for instance, the names and email addresses of any and all persons involved in communications that are contained or reflected in the records we have requested—and therefore makes clear that such information can only "help [HHS]" (let alone be required as a condition of processing a given FOIA request) "***if available***." 45 C.F.R. § 5.22(a)(4) (emphasis added). That commonsense recognition precisely describes this matter. By its plain terms, the Request seeks information about communications to which Exela was not a party. Requesters do not know, and cannot know, every single person at HHS who may have had communications about the Request's subject matter with outside parties, let alone every single person outside of HHS who may have had communications with HHS about that subject matter. Indeed, the whole point of the Request is to determine ***whether*** there were such communications, ***who*** was involved in such communications, and ***what*** those communications were. FOIA in turn makes it your responsibility to find that information for us—not force us to divine and disclose the unknowable as a condition of complying with your statutory obligations.

That having been said, Requesters certainly understand that compliance with your FOIA obligations may require you to run a variety of email searches given the alleged limitations of your email system (though we note that is a problem for which Requesters assuredly are not responsible, and which does not otherwise justify HHS's refusal to process the Request). HHS of course maintains names and contact information for all staff within the identified Offices (including, for example, HHS's Office of the General Counsel, Office of the Assistant Secretary for Health, and/or the Immediate Office of the Secretary). And Requesters have no objection to you running individual searches for responsive documents on an employee-by-employee basis if it really is true

that your email system is incapable of running searches on a broader basis (again, however, we note that your own FOIA regulation expressly provides that requests can be made, and therefore can be processed, on an agency- or office-wide basis, and not merely on an individual-by-individual basis, *see* 45 C.F.R. § 5.22(a)(1)).

To the extent it would further assist your efforts, ***and without limiting the scope of the Request in any way***, we might suggest your search of emails begin with the following HHS custodians:

1. Xavier Becerra – Xavier.Becerra@hhs.gov
2. Sean McCluskie – Sean.Mccluskie@hhs.gov
3. Angela Ramirez – Angela.Ramirez@hhs.gov
4. Anne Reid – Anne.Reid@fda.hhs.gov
5. Stephen Cha – Stephen.Cha@hhs.gov
6. Karuna Seshasai – Karuna.Seshasai@hhs.gov
7. Elizabeth Gramling – Elizabeth.Gramling@hhs.gov
8. Kashif Syed – TauheedAliKashif.Syed@hrsa.hhs.gov
9. Samuel Bagenstos – Samuel.Bagenstos@hhs.gov
10. Andrea Palm – Andrea.Palm@hhs.gov
11. Angela Botticella – Angela.Botticella@hhs.gov
12. Melanie Egorin – Melanie.Egorin@hhs.gov
13. Rose Sullivan – Rose.Sullivan@hhs.gov
14. Madeline Daly - Madeline.Daly@hhs.gov
15. Kimberly Espinosa - Kimberly.Espinosa@hhs.gov
16. Alex Graf - Alex.Graf@hhs.gov
17. Steven "Jeff" Hild - Jeff.Hild@acf.hhs.gov
18. Peter Rechter – Peter.Rechter@hhs.gov
19. Leslie Zelenko – Leslie.Zelenko@hhs.gov
20. Staceye Arrington – Staceye.Arrington@hhs.gov
21. William Brady – William.Brady@hhs.gov
22. Caitlin Fross – Caitlin.Fross@hhs.gov
23. Syed Mohiuddin – Syed.Mohiuddin @hhs.gov
24. Remi Roberts – Remi.Roberts@hhs.gov
25. Adm. Rachel L. Levine, MD – Rachel.Levine@hhs.gov
26. Sarah Boateng – Sarah.Boateng@hhs.gov
27. Maura Calsyn – Maura.Calsyn@hhs.gov
28. Michael Iademarco – Michael.Iademarco@hhs.gov
29. Mirabelle Adamu – Mirabelle.Adamu@hhs.gov
30. Evan Sturtevant – Evan.Sturtevant@hhs.gov
31. Steven Rush – Steven.Rush@hhs.gov
32. Keian Weld – Keian.Weld1@hhs.gov
33. HHS Counselors – HHS.Counselors@hhs.gov

Please also request that any custodians review personal email addresses for responsive documents.

We also are pleased to provide the following key search terms to help facilitate your identification of records—whether contained in emails or otherwise—that may be responsive to the Request:

"aluminum," "cysteine," "Nivagen," "Sandoz," "Eton," "Exela," "small volume parenteral," and/or "SVP."

Finally, and as the Request previously noted, Requesters ask that responsive documents be made available as soon as they are located and reviewed *via* a rolling production—a request that is all the more important given that your Clarification Letter raises concerns ***only*** with respect to HHS's search of email-based records, and ***not*** any of the other types of records that might be responsive to the Request. To the extent you continue to have concerns about the email component of the Request after considering this correspondence, we reiterate that there is no lawful basis for refusing to search your other systems/locations for responsive documents and remind you of HHS's statutory obligation to respond to the Request within 20 days. 5 U.S.C. § 552(a)(6)(A).

If you have further questions about this request, we respectfully suggest that a telephone conference with me and my outside counsel might be the most efficient course of action. Please let me know if and when you would like discuss these issues.

Best regards,

Phanesh Koneru Digitally signed by Phanesh Koneru Date: 2023.03.19 23:34:33 -04'00'

Phanesh Koneru
Chief Executive Officer
(703) 964-7884
pkoneru@exela.us

Bridget Archer 3-19-2023

Bridget Archer
Pharmacist-in-Charge
(704) 301-7687
barcher@exela.us

EXHIBIT 6

From: Ken Daines <KDaines@HoltzmanVogel.com>
Sent: Monday, March 20, 2023 11:35 AM
To: Noussoukpoe, Ray (OS/ASPA) <Ray.Noussoukpoe@hhs.gov>
Cc: Jason Torchinsky <jtorchinsky@HoltzmanVogel.com>; Sharon Norwood <snorwood@HoltzmanVogel.com>
Subject: RE: HHS FOIA Clarification Letter -- 2023-00557-FOIA-OS

Mr. Noussoukpoe,

Please see the attached three letters responding to your requests for clarification regarding **Case Nos. 2023-00555-FOIA-OS, 2023-00557-FOIA-OS, and 2023-00558-FOIA-OS.**

Please let us know if we can provide additional clarification on any of these issues.

Thank you,

Ken Daines
Holtzman Vogel Baran Torchinsky & Josefiak PLLC
KDaines@HoltzmanVogel.com // www.HoltzmanVogel.com

From: Noussoukpoe, Ray (OS/ASPA) <Ray.Noussoukpoe@hhs.gov>
Sent: Friday, March 17, 2023 10:31 AM
To: Ken Daines <KDaines@HoltzmanVogel.com>
Cc: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>; Sharon Norwood <snorwood@HoltzmanVogel.com>
Subject: FW: HHS FOIA Clarification Letter -- 2023-00557-FOIA-OS

> Some people who received this message don't often get email from ray.noussoukpoe@hhs.gov. Learn why this is important

Dear Ken Daines,
Thank you for your email.
Attached is **#2023-00557-FOIA-OS** clarification letter and sorry for any inconvenience.

Waiting for your clarification regarding all three (3) **#2023-00555-FOIA-OS, 2023-00557-FOIA-OS, and 2023-00558-FOIA-OS** requests to proceed

Warm Regards,

Ray

Ray Noussoukpoe, MPA
Government Information Specialist
FOI/PA / ASPA / OS
US Dept. of HHS

From: Ken Daines <KDaines@HoltzmanVogel.com>
Sent: Wednesday, March 15, 2023 2:24 PM
To: OS FOIA Request (HHS/ASPA) <FOIARequest@hhs.gov>
Cc: Jason Torchinsky <jtorchinsky@HoltzmanVogel.com>; Sharon Norwood <snorwood@HoltzmanVogel.com>
Subject: FW: HHS FOIA Clarification Letter -- 2023-00557-FOIA-OS

Mr. Noussoukpoe,

We are in receipt of your email today titled "HHS FOIA Clarification Letter" regarding Mr. Koneru's FOIA request. Based on your email, it appears that you meant to send us a letter for **Case No. 2023-00557-FOIA-OS**, but the attached letter is addressed to a different FOIA request, **2023-00558-FOIA-OS**. Please send us the letter for 2023-00557-FOIA-OS.

Thank you,

Ken Daines
Holtzman Vogel Baran Torchinsky & Josefiak PLLC
KDaines@HoltzmanVogel.com // www.HoltzmanVogel.com

From: Noussoukpoe, Ray <foiarequest@hhs.gov>
Sent: Wednesday, March 15, 2023 4:14 PM
To: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>
Subject: HHS FOIA Clarification Letter -- 2023-00557-FOIA-OS

Hello, Phanesh Koneru

Attached is a Clarification Letter to your FOIA request 2023-00557-FOIA-OS. If you have any questions, please contact

HHS FOIA Office at FoiaRequest@hhs.gov.

Thank You

EXHIBIT 7

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Refer to: Request Number **2023-00558-FOIA-OS**

March 28, 2023

Sent via email:
Phanesh Koneru
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This acknowledges receipt of your March 14, 2023, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning **"All records relating to development, drafting, and/or publication of the December Draft Guidance titled Small volume parenteral drug products and pharmacy bulk packages for parenteral nutrition: Aluminum content and labeling recommendations ... (Date Range for Record Search: From 1/1/2021 To 3/14/2023)".**
We received your request on March 14, 2023.

Because you seek records which require a search in another office, "unusual circumstances" apply to your request, automatically extending the time limit to respond to your request for ten additional days. See 5 U.S.C. 552 § (a)(6)(B)(i)-(iii) (2012 & Supp. V. 2017). Further, we estimate needing more than 10 additional days to respond to your request and so, in the next paragraph of this letter we are offering you an opportunity to narrow your request, in case narrowing the request would enable us to respond to the request sooner. The actual time needed to process your request will depend on the complexity of our records search and on the volume and complexity of any material located. For your information, this Office assigns incoming requests to one of three tracks: simple, complex, or expedited. Each request is then handled on a first-in, first-out basis in relation to other requests in the same track. Our current workload is approximately 3000 cases.

Your request is assigned to the complex track. In an effort to speed up our records search, you may wish to narrow the scope of your request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located. You may also wish to await the completion of our records search to discuss either of these options.

I regret the necessity of this delay, but I assure you that your request will be processed as soon as possible. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Ray Noussoukpoe at FoiaRequest@PSC.hhs.gov.

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)

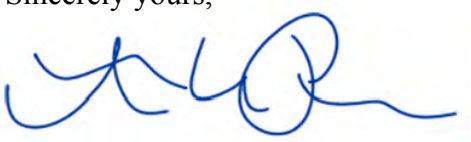
Telephone: (202) 690-7453
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

and/or:

Office of Government Information Services
National Archives and Records Administration
Telephone: 202- 741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

If you are not already submitting your requests through our Public Access Link (PAL), we recommend all future requests and appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting requests through PAL automatically logs your requests into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your request, receive your documents directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

Sincerely yours,



Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division

EXHIBIT 8

From: Noussoukpoe, Ray <foiarequest@hhs.gov>
Sent: Tuesday, March 28, 2023 1:35 PM
To: Jason Torchinsky <jtorchinsky@HoltzmanVogel.com>
Subject: HHS FOIA Acknowledgement Letter -- 2023-00558-FOIA-OS

Dear Phanesh Koneru

Please see the attached Acknowledgement Letter in response to your FOIA Request submitted to the Department of Health and Human Services (HHS) via E-mail on March 14, 2023.
The letter contains important information concerning your FOIA matter which has been assigned tracking number **2023-00558-FOIA-OS**.
For status updates or other inquiries, please contact our office via email at FOIARequest@hhs.gov. *Please include your tracking number in the subject line of your inquiry,*

Sincerely,

HHS FOIA Office

EXHIBIT 9

From: noreply@ains.com
Date: March 28, 2023 at 1:42:05 PM EDT
To: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>
Subject: Status Update for Request #2023-00558-FOIA-OS

Dear Phanesh Koneru,

The status of your FOIA request #2023-00558-FOIA-OS has been updated to the following status 'In Process'. To log into the HHS FOIA Submission Site click on the Application URL below.

https://requests.publiclink.hhs.gov

Sincerely,
U.S. Department of Health & Human Services

EXHIBIT 10

Holtzman Vogel

HOLTZMAN VOGEL BARAN TORCHINSKY & JOSEFIAK PLLC

April 18, 2023

Arianne Perkins
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

RE: STATUS OF REQUEST FOR EXPEDITED PROCESSING AND NARROWING SCOPE OF REQUEST (FOI/PA Request No. 2023-00558-FOIA-OS)

Ms. Perkins,

On March 13, 2023, my client, Exela Pharma Sciences, LLC ("Exela"), through its Chief Executive Officer, Phanesh Koneru, and Pharmacist-In-Charge, Bridget Archer, submitted a request for records from HHS under the Freedom of Information Act ("FOIA"). 5 U.S.C. § 552; 45 C.F.R.§ 5.21. (Attachment 1). HHS acknowledged that the request was received on March 14, 2023, and that it has been assigned FOI/PA number 2023-00558-FOIA-OS. (Attachment 2). Exela's request letter includes an application for expedited processing and outlines the reasons that expedited treatment of this request is warranted under 45 C.F.R. § 5.27 and 5 U.S.C. § 552(a)(6)(E).

To date, Exela has not received a determination in response to its request for expedited processing. 45 C.F.R. § 5.27(c) states that HHS will respond to requests for expedited processing "within 10 calendar days of [its] receipt of [the] request to expedite." *See also* 5 U.S.C. § 552(a)(6)(E)(ii) ("[N]otice of the determination [of whether to provide expedited processing] shall be provided to the person making the request, within 10 days after the date of the request."). This means that the statutory deadline for a response passed three weeks ago on March 24, 2023. Accordingly, we request that HHS immediately respond with a determination regarding Exela's request for expedited processing as statutorily required.

Separately, we received a letter from your office dated March 28, 2023 indicating that Exela "may wish to narrow the scope of [its] request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located." (Attachment 3). Without waiving, tolling, or resetting the FOIA statutory twenty-day (or thirty-day under "unusual circumstances") requirement for a response under 45 C.F.R. § 5.24 and 5 U.S.C. §§ 552(a)(6)(A) and (a)(6)(B), our client is willing to narrow the scope of the request to ensure HHS makes a determination and produces responsive records within the statutory time frame.

Accordingly, instead of the original date range of January 1, 2021 through the date of production, we propose a narrowed date range of December 1, 2021 through the date of production.

Please confirm whether this would enable HHS to process Exela's March 14, 2023 FOIA request within the time frame mandated by FOIA. To reiterate, this proposal should not be construed as a request to create a new or separate FOIA request. Please confirm if you are amenable to narrowing the scope in this manner.

I welcome the opportunity to discuss this with you further and can be reached at jtorchinsky@holtzmanvogel.com.

Sincerely,

Jason Torchinsky
Holtzman Vogel Baran Torchinsky & Josefiak PLLC

Attachments

EXHIBIT 11

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00558-FOIA-OS

April 20, 2023

Sent via email:
Phanesh Koneru
Exela Pharma Sciences, LLC
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This is an interim response to your March 14, 2023, Freedom of Information Act (FOIA) request.

You requested the following: (All records relating to development, drafting, and/or publication of the December Draft Guidance titled Small volume parenteral drug products and pharmacy bulk packages for parenteral nutrition: Aluminum content and labeling recommendations ... (Date Range for Record Search: From 1/1/2021 To 3/14/2023)).

HHS FOIA Office has determined your request for expedited processing does not meet the requirements under the FOIA and HHS implementing regulations and cannot be granted. The FOIA requires an agency expedite processing of a request only when the requester demonstrates a "compelling need."

Our review indicates you have not clearly demonstrated a "compelling need," because you have not clearly articulated an imminent threat to the life or physical safety of an individual; and you also have not demonstrated that there is an "urgency to inform the public concerning actual or alleged Federal activity" through a request by one primarily engaged in disseminating information to the public.

The law authorizes us to collect fees for responding to FOIA requests. However, because we are uncertain that applicable fees will exceed our minimum charge ($25.00), we are not addressing your request for a fee waiver at this time. Nevertheless, if we determine there will be fees associated with processing your request, we will contact you at that time.

The Department of Health and Human Services regulations allows us to recover part of the costs associated with the processing of FOIA requests. It was determined that your request will be processed under the "Commercial" category; therefore, your request may be subject to duplication fees at .10 cents per page after the first 100 pages of duplication. We will notify you if it appears that the fees will exceed the limit in which you set.

If you are not satisfied with my action on this request, you may administratively appeal this denial of expedited processing. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Please mark the correspondence, "Freedom of Information Act Appeal." Your appeal must be transmitted within 90 days from the date of receipt of this letter to:

William Holzerland
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
HHS.ACFO@hhs.gov

If you choose to mail your appeal, please clearly mark both the envelope and your letter "Freedom of Information Act Appeal." The mailing address is: Room 729H, 200 Independence Avenue, SW, Washington, DC 20201. Please note the entire office is working remotely and appeals sent by mail may receive delayed receipt dates.

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, you may contact the HHS FOIA Public Liaison for assistance at:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW, Suite 729H
Washington, DC 20201

Telephone: (202) 690-7453
Fax: (202) 690-8320
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001

Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

Sincerely yours

Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division

EXHIBIT 12

EXELA
PHARMA SCIENCES
1245 Blowing Rock Blvd
Lenoir, NC 28645
www.exelapharma.com

March 13, 2023

Arianne Perkins
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Freedom of Information Act (FOIA) Request

Dear Freedom of Information Officer:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and HHS's FOIA implementing regulations, 45 C.F.R. § 5.21 *et seq*., Phanesh Koneru, Bridget Archer, and Exela Pharma Sciences, LLC (collectively "Requesters") hereby request the following records[1] in HHS's possession on or after January 1, 2021 through the date of production:

1. Any records relating to Abbreviated New Drug Application ("ANDA") 213073, including, to the maximum extent possible, all communications within HHS (including any Office, Division (other than the U.S. Food and Drug Administration ("FDA")[2]), or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees) and the sponsor of ANDA 213073 (Nivagen Pharmaceuticals), regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).

[1] "Records," as that term is defined under FOIA (5 U.S.C. § 552(f)(2)), and under applicable case law (*see, e.g.*, *Forsham v. Harris*, 445 U.S. 169, 193 (1980)) include, but are not limited to, written correspondence, memoranda, records kept in electronic format on computers and/or electronic storage devices, email correspondence (whether through .gov email addresses or private third-party services such as Gmail), records of telephone correspondence, records pertaining to in-person meetings, calendar or scheduling entries, videotapes, photographs, computer print-outs, telephone messages, or voicemail messages.

[2] Requesters have filed separate FOIA requests directly with FDA and therefore do not need HHS to search FDA's records for responsive documents.

2. Any records relating to Abbreviated New Drug Application ("ANDA") 214082, including, to the maximum extent possible, all communications within HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees) and the sponsor of ANDA 214082 (Eton Pharmaceuticals), regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).

3. Any records relating to Abbreviated New Drug Application ("ANDA") 209994, including, to the maximum extent possible, all communications within HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and the sponsor of ANDA 209994 (Sandoz) regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).

Requesters believe that responsive records are most likely to be located in HHS's Immediate Office of the Secretary, Office of the Assistant Secretary for Health, and Office of the General Counsel. To facilitate your compliance with FOIA's 20-day deadline, *see* 5 U.S.C. § 552(a)(6)(A), please produce records on a rolling basis, as soon as responsive records are located and reviewed. To the extent you identify any additional records relating to aluminum content, Requesters ask that you review and include such records in the first batch of documents produced. Along with our outside counsel, Requesters would be pleased to discuss this request with you if doing so could help facilitate a timely response.

Finally, Requesters ask that HHS process this request consistent with the Department of Justice's policy memorandum (directed to the heads of executive departments and agencies) emphasizing the presumption of disclosure under FOIA, as amended by the FOIA Improvement Act of 2016.[3]

Request for Expedited Processing: Requesters further request that HHS provide expedited processing of this FOIA request. This request qualifies for expedited treatment pursuant to 45 C.F.R. § 5.27(b)(1) and 5 U.S.C. § 552(a)(6)(E) because the lack of publicly available information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of an individual," 5 U.S.C. § 552(a)(6)(E)(v)(I), including many preterm infants—whose lives depend on using these products, but who may be seriously harmed by exposure to unsafe levels of aluminum contamination in the process.[4]

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[3] Dep't of Justice Office of Information Policy, Memorandum from The Attorney General, March 15, 2022, *available at* https://www.justice.gov/ag/page/file/1483516/download (last visited September 10, 2022).

[4] *See, e.g.*, Mark R. Corkins, "Review finds greatest risk of aluminum exposure is via parenteral nutrition," American Academy of Pediatrics News, Nov. 25, 2019, *available at* https://publications.aap.org/aapnews/news/13404 (last visited Mar. 6, 2023); Mark R. Corkins, Praveen S. Goday, and Ellen S. Rome, "Aluminum Effects in Infants and Children," American Academy of Pediatrics, vol. 144, no. 6 (Dec. 2019), *available at* https://publications.aap.org/pediatrics/article/144/6/e20193148/37901/Aluminum-Effects-in-Infants-and-Children?autologincheck=redirected (last visited Mar. 6, 2023); Heather A. Wier and Robert J. Kuhn, "Aluminum Toxicity in Neonatal Parenteral Nutrition: What Can We do?" SAGE Journals, vol 45, no. 1 (Jan. 2012), *available at* https://journals.sagepub.com/doi/10.1345/aph.1Q399 (last visited Mar. 6, 2023).

L-cysteine is a necessity for proper human life functioning. While healthy adults can naturally synthesize small amounts of L-cysteine, certain high-risk patients—including preterm and/or low birth weight infants and patients with severe liver disease—require L-cysteine supplementation by parenteral administration. Aluminum toxicity in the administration of such treatment can cause serious health problems, including bone toxicity, dementia, impaired neurologic development, Alzheimer's disease, and liver disease, among other conditions. Federal regulation of aluminum in these products thus has a direct impact on the health and safety of society's most vulnerable individuals, and the lack of publicly available information concerning aluminum levels in cysteine products "could reasonably be expected to pose an imminent threat to the life or physical safety," *id.*; 45 C.F.R. § 5.27(b)(1), by depriving healthcare professionals of critical information needed to ensure the health and safety of highly vulnerable patients, including preterm infants who require total parenteral nutrition ("TPN") and adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. Patients with underlying renal impairment who receive prolonged courses of parenteral nutrition support are at greatest risk of exposure to toxic levels of aluminum from parenteral nutrition. Obtaining the requested records regarding these government activities is necessary to protect the health of these vulnerable individuals.

As required by federal regulation, the undersigned certify that the above information is true and correct to the best of their knowledge and belief.

Search and Processing of Requested Records: Upon receipt of this request, please take all reasonable steps to preserve relevant public records while the request is pending. Please also contact us promptly to provide an estimated date on which you will finish processing this request. Notice is hereby given that the Requesters request an estimation of appropriate fees incurred and assessed for the "document search and duplication" of the department records responsive to this request if such fees should exceed $250.00. 5 U.S.C. § 552(a)(4)(A)(ii)(III).

Please search for responsive records regardless of format, medium, or physical characteristics. Requesters ask that responsive electronic records be produced electronically in their native file format, if possible, or the format most felicitous to an expedited production. Alternatively, Requesters request that the Records be provided electronically in text-searchable PDF, in the best image quality in HHS's possession, and in separate, Bates-stamped files.

If this FOIA request is denied in whole or in part, please provide the reasons for the denial, pursuant to 5 U.S.C. § 552(a)(6)(A)(i). If it is your position that any portion of the requested records is exempt from disclosure, we request that you provide a *Vaughn* index of those documents. *See Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973). As you are aware, a *Vaughn* index must describe each document claimed as exempt with sufficient specificity "to permit a reasoned judgment as to whether the material is actually exempt under FOIA." *Founding Church of Scientology v. Bell*, 603 F.2d 945, 959 (D.C. Cir. 1979). Moreover, the *Vaughn* index must "describe each document or portion thereof withheld, and for each withholding it must discuss the consequences of supplying the sought- after information." *King v. U.S. Dep't of Justice*, 830 F.2d 210, 223–24 (D.C. Cir. 1987).

In the event that some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable, non-exempt portions of the requested records. *See* 5

U.S.C. § 552(b). Pursuant to regulation, please clearly delineate any and all redactions in such a manner so that the justification for each redaction is apparent. If it is your position that a document contains non-exempt segments and that those non-exempt segments are so dispersed throughout the documents as to make segregation impossible, please state what portion of the document is non-exempt, and how the material is dispersed through the document. *Mead Data Cent. v. U.S. Dep't of the Air Force*, 455 F.2d 242, 261 (D.C. Cir. 1977). Claims of non-segregability must be made with the same detail as required for claims of exemptions in a *Vaughn* index. If a request is denied in whole, please state specifically that it is not reasonable to segregate portions of the record for release.

For records available in electronic format, please email the documents to jtorchinsky@holtzmanvogel.com. Please send all other requested documents to the attention of:

Holtzman Vogel Baran Torchinsky & Josefiak
Attn: Jason Torchinsky
2300 N. St. NW Ste. 643A
Washington, D.C. 20037

Finally, we reiterate our request that responsive documents be made available as soon as they are located and reviewed *via* a rolling production. Requesters will pay reasonable increased costs incurred to facilitate a rolling production.

If you have any questions about this request, please do not hesitate to contact either me or my counsel.

Phanesh Koneru
Digitally signed by Phanesh Koneru
Date: 2023.03.13 12:00:38 -04'00'

Phanesh Koneru
Chief Executive Officer
(703) 964-7884
pkoneru@exela.us

Bridget Archer 3-13-2023

Bridget Archer
Pharmacist-in-Charge
(704) 301-7687
barcher@exela.us

EXHIBIT 13

From: noreply@ains.com
Date: March 14, 2023 at 2:33:00 PM GMT+1
To: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>
Subject: Request Acknowledgement by U.S. Department of Health & Human Services

You don't often get email from noreply@ains.com. Learn why this is important

Dear Phanesh Koneru,

Your request has been received by the U.S. Department of Health & Human Services. The request has been assigned tracking # 2023-00557-FOIA-OS, please log into your account and review your submission.

The
application address is https://requests.publiclink.hhs.gov.

Thank you,
U.S. Department of Health & Human Services

EXHIBIT 14

Subject: FW: HHS FOIA Clarification Letter -- 2023-00557-FOIA-OS
Attachments: HHS FOIA -- 2 Specific ANDAs.pdf; Clarification Letter.pdf

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From: Noussoukpoe, Ray <foiarequest@hhs.gov>
Sent: Wednesday, March 15, 2023 4:14 PM
To: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>
Subject: HHS FOIA Clarification Letter -- 2023-00557-FOIA-OS

Hello, Phanesh Koneru

Attached is a Clarification Letter to your FOIA request 2023-00557-FOIA-OS. If you have any questions, please contact HHS FOIA Office at FoiaRequest@hhs.gov.

Thank You

EXHIBIT 15

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00557-FOIA-OS

March 15, 2023

Sent via email:
Phanesh Koneru
Exela Pharma Sciences, LLC
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This clarification letter is in response to your March 14, 2023, Freedom of Information Act (FOIA) request. Specifically, you requested the following:

> ***"1) any records relating to Abbreviated New Drug Application ("ANDA) 213073 ... regarding aluminum content...***
> ***2) any records relating to Abbreviated New Drug Application ("ANDA) 214082 ... regarding aluminum content...***
> ***any records relating to Abbreviated New Drug Application ("ANDA) 209994 ... regarding aluminum content... (Date Range for Record Search: From 1/1/2021 To 3/14/2023)."***

The FOIA allows the public to request access to "reasonably described" existing agency records (subject to any applicable FOIA exemptions to disclosure). This means you must describe the category of records you are seeking or the actual document(s), and provide sufficient details to permit a search with reasonable effort, utilizing existing indices and search tools.

In accordance with Title 45 Code of Federal Regulations Subtitle A, Subpart B – How to Request Records under FOIA, HHS outlined what must be contained in FOIA requests to allow staff to locate requested records with a reasonable amount of effort. As set out in HHS FOIA Regulations,

> "….. a written description of the records you seek in sufficient detail to enable our staff to locate them with a reasonable amount of effort. The more information you provide, the better possibility we have of finding the records you are seeking. Information that will help us find the records would include:
>
> (1) The agencies, offices, or individuals involved;
> (2) The approximate date(s) when the records were created;
> (3) The subject, title, or description of the records sought; and
> (4) Author, recipient, case number, file designation, or other reference number, if available."

This letter is to obtain clarification regarding your FOIA request.

Unfortunately, you have not described the records with enough specificity to allow us to continue with the processing of your request. As stated in line one (1) name of all HHS employees involved and any other individuals (**external to HHS if any**) involved name and email domain names are required.
In other words, **name of HHS employees and name and email domain names of all external individuals** who communicate "any records relating to Abbreviated New Drug Application" are needed to conduct an electronic search for records.

Additionally, provide search key "terms" or "words" to use for an effective and efficient search.

The Office of the Chief Information Officer reports due to technology constraints, HHS cannot run a blind search against all users in HHS or an operating/staff division. Electronic searches run against our live email system and a search against all HHS employees would crash our system.

Regarding the search terms, we would need the domain names for each entity in the list so that we could identify emails to or from a custodian to those entities. For example, "emails to or from Jane Doe (Jane.Doe@hhs.gov) and @organization.org or @commercial_entity.com" with specific key words and date ranges.

Once you provide the above information/details clarifying you request, we can conduct a search.

At this time, we have placed your request in "tolled" status. Therefore, please clarify and describe the records you are seeking, by sending an email to Ray Noussoukpoe, of my staff, at FOIARequest@hhs.gov.

After you further advise us what records you are seeking, we can begin to process your FOIA request.

HHS "may deny your request for other reasons, including that a request does not reasonably describe the records sought" in accordance with the HHS FOIA Regulations cited in paragraph three. If you have not contacted our office within 30 business days from the date of this letter, your request will be administratively closed. Therefore, no action on your part is needed, if you no longer have a need for the records.

Sincerely yours,

Arianne Perkins
Director
FOI/Privacy Acts Division

EXHIBIT 16

EXELA
PHARMA SCIENCES
1245 Blowing Rock Blvd
Lenoir, NC 28645
www.exelapharma.com

March 19, 2023

Arianne Perkins
Freedom of Information Officer
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Case No. 2023-00557-FOIA-OS

Ms. Perkins:

I write in response to your March 15, 2023 letter (the "Clarification Letter") requesting additional information with respect to the above-captioned FOIA request (the "Request"). As you know, that Request sought:

1. Any records relating to Abbreviated New Drug Application ("ANDA") 213073, including, to the maximum extent possible, all communications within HHS (including any Office, Division (other than the U.S. Food and Drug Administration ("FDA")[1]), or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees) and the sponsor of ANDA 213073 (Nivagen Pharmaceuticals), regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).

2. Any records relating to Abbreviated New Drug Application ("ANDA") 214082, including, to the maximum extent possible, all communications within HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees) and the sponsor of ANDA 214082 (Eton Pharmaceuticals), regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).

[1] Requesters have filed separate FOIA requests directly with FDA and therefore do not need HHS to search FDA's records for responsive documents.

3. Any records relating to Abbreviated New Drug Application ("ANDA") 209994, including, to the maximum extent possible, all communications within HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and the sponsor of ANDA 209994 (Sandoz) regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).

Request at 1 & n.1. In an effort to facilitate your compliance with FOIA, the Request further observed "that responsive records are most likely to be located within HHS's Immediate Office of the Secretary, Office of the Assistant Secretary for Health, and Office of the General Counsel." *Id.* at 2.

Despite the specificity of our Request—which, generally speaking, seeks all records regarding communications within HHS regarding the relevant ANDAs and their aluminum content—the Clarification Letter asserts that the Request did "not describe[] the records with enough specificity" simply because it did not provide the "name of all HHS employees involved and any other individuals **(external to HHS if any)** involved name and email domains are required." Clarification Ltr. at 1-2 (all emphases as in original). The Clarification Letter further suggests that HHS's FOIA regulations ***require*** us to provide this information as a condition of processing the Request. *Id.* at 1 ("In accordance with Title 45 Code of Federal Regulations Subtitle A, Subpart B – How to Request Records under FOIA, HHS outlined what must be contained in FOIA requests to allow staff to locate requested records with a reasonable amount of effort.").

Those assertions are incorrect: The cited regulation does not remotely require FOIA requesters to identify each (or any) of the particular individuals who may have been involved in creating certain responsive records (whether as an author or recipient) or to supply any of the additional information you have demanded.[2] Instead, the cited regulation merely identifies certain kinds of "[i]nformation ***that will help us*** find the records you are seeking" and then lists as, illustrative examples, "the agencies, offices, ***or*** individuals involved" and the "author, recipient, case number, file designation, or other reference number, ***if available***." 45 C.F.R. § 5.22(a)(1), (4) (both emphases added). The Clarification Letter's assertion that this regulation somehow "require[s]" Requesters to provide the information you have demanded therefore is triply flawed.

First, the courts have held that substantially similar FOIA regulations—which merely identify useful categories of information that would be helpful to the processing federal agency—do ***not*** in fact require FOIA requesters to supply all (or indeed any) such information as a condition of

[2] We note that the only concerns your response articulates relate to email searches. Clarification Letter at 2 (demanding that Requesters provide "email domain names"); *id.* (complaining that "HHS cannot run a blind search against all users in HHS or an operating/staff division" because "our live email system … would crash"); *id.* (seeking domain name information "so that we could identify emails to or from a custodian to those entities"). But the Request is not limited to emails; it seeks "***All records*** containing or reflecting communications" between HHS and outside parties regarding the specified subject matter, Request at 1 (emphasis added)—some of which may be contained in emails, and some of which may be contained in other Department records. *Id.* at 1 n.1 (defining the term "records"). You therefore have provided no basis for refusing to commence a search of your other systems for responsive records, and Requesters accordingly reject the Clarification Letter's assertion that the deadline for responding to this Request has been, or legitimately can be, "tolled." *Cf.* Clarification Letter at 2.

processing a FOIA request. *See, e.g., Biear v. Attorney General of the United States*, 905 F.3d 151, 156 (3d Cir. 2018) ("The government contends that Biear's request was insufficiently detailed, in part because it failed to suggest specific sections [of the Department of Justice] in which responsive records might be maintained. The text of the regulation does not require that a request contain that information. It states only that a request should contain that information '[t]o the extent possible.'") (discussing 28 C.F.R. § 16.3(b) ("Requesters must describe the records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount of effort. To the extent possible, requesters should include specific information that may assist a component in identifying the requested records, such as the date, title or name, author, recipient, subject matter of the record, case number, file designation, or reference number.")). HHS's regulation does not differ materially from the Department of Justice's: Just like DOJ's regulation, HHS's regulation begins by asserting that FOIA requesters must describe "the records you seek in sufficient detail to enable our staff to locate them with a reasonable amount of effort," and then identifies certain categories of "information that will help us … if available." 45 C.F.R. § 5.22(a). It does not, however, ***require*** FOIA requesters to supply any such information (whether available or not) as a condition of fulfilling the request, just as the courts have made clear that DOJ's substantially similar regulation includes no such requirement. *See Biear*, 905 F.3d at 156.

Second, the Request fully complied with your regulation in any event. Whether or not the regulation requires Requesters to supply certain categories of information (and it doesn't, for the reasons we have just explained), the Request did exactly what the regulation expressly authorizes: It specifically identified "the agencies, offices, ***or*** individuals involved," 45 C.F.R. § 5.22(a) (emphasis added), by noting "that responsive records are most likely to be located within HHS's Immediate Office of the Secretary, Office of the Assistant Secretary for Health, and Office of the General Counsel." Request at 2. Needless to say, each of the identified "Office[s]" is an "office" within the meaning of 45 C.F.R. § 5.22(a). And the regulation's disjunctive use of the word "***or***" makes clear that FOIA requesters are ***not*** required to supply the names of all "agencies, offices, ***and*** individuals involved" (assuming, for the sake of argument, that it requires anything at all). Any one of those alternatives suffices, and the Request supplied them. *See, e.g., In re Espy*, 80 F.3d 501, 505 (D.C. Cir. 1996) ("[A] statute written in the disjunctive is generally construed as setting out separate and distinct alternatives."); *cf. Loving v. IRS*, 742 F.3d 1013, 1019 (D.C. Cir. 2014) ("[T]he statute uses the conjunctive 'and' — not the disjunctive 'or' — when listing the various requirements, a strong indication that Congress did not intend the requirements as alternatives.").

Finally, the cited regulation expressly acknowledges that FOIA requesters may not have the information you are demanding Requesters now provide—here, for instance, the names and email addresses of any and all persons involved in communications that are contained or reflected in the records we have requested—and therefore makes clear that such information can only "help [HHS]" (let alone be required as a condition of processing a given FOIA request) "***if available***." 45 C.F.R. § 5.22(a)(4) (emphasis added). That commonsense recognition precisely describes this matter. By its plain terms, the Request seeks information about communications to which Exela was not a party. Requesters do not know, and cannot know, every single person at HHS who may have had communications about the Request's subject matter with outside parties, let alone every single person outside of HHS who may have had communications with HHS about that subject matter. Indeed, the whole point of the Request is to determine ***whether*** there were such communications, ***who*** was involved in such communications, and ***what*** those communications

were. FOIA in turn makes it your responsibility to find that information for us—not force us to divine and disclose the unknowable as a condition of complying with your statutory obligations.

That having been said, Requesters certainly understand that compliance with your FOIA obligations may require you to run a variety of email searches given the alleged limitations of your email system (though we note that is a problem for which Requesters assuredly are not responsible, and which does not otherwise justify HHS's refusal to process the Request). HHS of course maintains names and contact information for all staff within the identified Offices (for example, in tbe Immediate Office of the Secretary, Office of the Assistant Secretary for Health, and Office of the General Counsel). And Requesters have no objection to you running individual searches for responsive documents on an employee-by-employee basis if it really is true that your email system is incapable of running searches on a broader basis (again, however, we note that your own FOIA regulation expressly provides that requests can be made, and therefore can be processed, on an agency- or office-wide basis, and not merely on an individual-by-individual basis, *see* 45 C.F.R. § 5.22(a)(1)).

To the extent it would further assist your efforts, ***and without limiting the scope of the Request in any way***, we might suggest your searcb of emails begin with the following HHS custodians:

1. Xavier Becerra – Xavier.Becerra@hhs.gov
2. Sean McCluskie – Sean.Mccluskie@hhs.gov
3. Angela Ramirez – Angela.Ramirez@hhs.gov
4. Anne Reid – Anne.Reid@fda.hhs.gov
5. Stephen Cha – Stephen.Cha@hhs.gov
6. Karuna Seshasai – Karuna.Seshasai@hhs.gov
7. Elizabeth Gramling – Elizabeth.Gramling@hhs.gov
8. Kashif Syed – TauheedAliKashif.Syed@hrsa.hhs.gov
9. Samuel Bagenstos – Samuel.Bagenstos@hhs.gov
10. Andrea Palm – Andrea.Palm@hhs.gov
11. Angela Botticella – Angela.Botticella@hhs.gov
12. Melanie Egorin – Melanie.Egorin@hhs.gov
13. Rose Sullivan – Rose.Sullivan@hhs.gov
14. Madeline Daly - Madeline.Daly@hhs.gov
15. Kimberly Espinosa - Kimberly.Espinosa@hhs.gov
16. Alex Graf - Alex.Graf@hhs.gov
17. Steven "Jeff" Hild - Jeff.Hild@acf.hhs.gov
18. Peter Rechter – Peter.Rechter@hhs.gov
19. Leslie Zelenko – Leslie.Zelenko@hhs.gov
20. Staceye Arrington – Staceye.Arrington@hhs.gov
21. William Brady – William.Brady@hhs.gov
22. Caitlin Fross – Caitlin.Fross@hhs.gov
23. Syed Mohiuddin – Syed.Mohiuddin @hhs.gov
24. Remi Roberts – Remi.Roberts@hhs.gov
25. Adm. Rachel L. Levine, MD – Rachel.Levine@hhs.gov
26. Sarah Boateng – Sarah.Boateng@hhs.gov
27. Maura Calsyn – Maura.Calsyn@hhs.gov
28. Michael Iademarco – Michael.Iademarco@hhs.gov

29. Mirabelle Adamu – Mirabelle.Adamu@hhs.gov
30. Evan Sturtevant – Evan.Sturtevant@hhs.gov
31. Steven Rush – Steven.Rush@hhs.gov
32. Keian Weld – Keian.Weld1@hhs.gov
33. HHS Counselors – HHS.Counselors@hhs.gov

Please also request that any custodians review personal email addresses for responsive documents.

We also are pleased to provide the following key search terms to help facilitate your identification of records—whether contained in emails or otherwise—that may be responsive to the Request: "aluminum," "cysteine," "Nivagen," "Sandoz," "Eton," "Exela," "small volume parenteral," and/or "SVP."

Finally, and as the Request previously noted, Requesters ask that responsive documents be made available as soon as they are located and reviewed *via* a rolling production—a request that is all the more important given that your Clarification Letter raises concerns ***only*** with respect to HHS's search of email-based records, and ***not*** any of the other types of records that might be responsive to the Request. To the extent you continue to have concerns about the email component of the Request after considering this correspondence, we reiterate that there is no lawful basis for refusing to search your other systems/locations for responsive documents and remind you of HHS's statutory obligation to respond to the Request within 20 days. 5 U.S.C. § 552(a)(6)(A).

If you have further questions about this request, we respectfully suggest that a telephone conference with me and my outside counsel might be the most efficient course of action. Please let me know if and when you would like discuss these issues.

Best regards,

Phanesh Koneru Digitally signed by Phanesh Koneru Date: 2023.03.19 23:32:46 -04'00'

Phanesh Koneru
Chief Executive Officer
(703) 964-7884
pkoneru@exela.us

Bridget Archer 3-19-2023

Bridget Archer
Pharmacist-in-Charge
(704) 301-7687
barcher@exela.us

EXHIBIT 17

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Refer to: Request Number **2023-00557-FOIA-OS**

March 28, 2023

Sent via email:
Phanesh Koneru
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This acknowledges receipt of your March 14, 2023, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning **"1) any records relating to Abbreviated New Drug Application ("ANDA) 213073 ... regarding aluminum content...**
2) any records relating to Abbreviated New Drug Application ("ANDA) 214082 ... regarding aluminum content...
any records relating to Abbreviated New Drug Application ("ANDA) 209994 ... regarding aluminum content... (Date Range for Record Search: From 1/1/2021 To 3/14/2023)".
We received your request on March 14, 2023.

Because you seek records which require a search in another office, "unusual circumstances" apply to your request, automatically extending the time limit to respond to your request for ten additional days. See 5 U.S.C. 552 § (a)(6)(B)(i)-(iii) (2012 & Supp. V. 2017). Further, we estimate needing more than 10 additional days to respond to your request and so, in the next paragraph of this letter we are offering you an opportunity to narrow your request, in case narrowing the request would enable us to respond to the request sooner. The actual time needed to process your request will depend on the complexity of our records search and on the volume and complexity of any material located. For your information, this Office assigns incoming requests to one of three tracks: simple, complex, or expedited. Each request is then handled on a first-in, first-out basis in relation to other requests in the same track. Our current workload is approximately 3000 cases.

Your request is assigned to the complex track. In an effort to speed up our records search, you may wish to narrow the scope of your request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located. You may also wish to await the completion of our records search to discuss either of these options.

I regret the necessity of this delay, but I assure you that your request will be processed as soon as possible. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Ray Noussoukpoe at FoiaRequest@PSC.hhs.gov.

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)

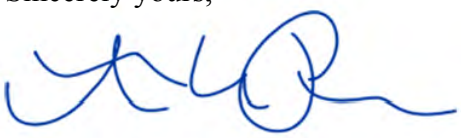
Telephone: (202) 690-7453
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

and/or:

Office of Government Information Services
National Archives and Records Administration
Telephone: 202- 741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

If you are not already submitting your requests through our Public Access Link (PAL), we recommend all future requests and appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting requests through PAL automatically logs your requests into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your request, receive your documents directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

Sincerely yours,



Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division

EXHIBIT 18

From: Noussoukpoe, Ray <foiarequest@hhs.gov>
Sent: Tuesday, March 28, 2023 1:15 PM
To: jtorchinsky@holtzmanvogel.com
Subject: HHS FOIA Acknowledgement Letter -- 2023-00557-FOIA-OS

Dear Phanesh Koneru

Please see the attached Acknowledgement Letter in response to your FOIA Request submitted to the Department of Health and Human Services (HHS) via E-mail on March 14, 2023.
The letter contains important information concerning your FOIA matter which has been assigned tracking number **2023-00557-FOIA-OS**.
For status updates or other inquiries, please contact our office via email at FOIARequest@hhs.gov. *Please include your tracking number in the subject line of your inquiry,*

Sincerely,

HHS FOIA Office

EXHIBIT 19

April 18, 2023

Arianne Perkins
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

RE: STATUS OF REQUEST FOR EXPEDITED PROCESSING AND NARROWING SCOPE OF REQUEST (FOI/PA Request No. 2023-00557-FOIA-OS)

Ms. Perkins,

On March 13, 2023, my client, Exela Pharma Sciences, LLC ("Exela"), through its Chief Executive Officer, Phanesh Koneru, and Pharmacist-In-Charge, Bridget Archer, submitted a request for records from HHS under the Freedom of Information Act ("FOIA"). 5 U.S.C. § 552; 45 C.F.R. § 5.21. (Attachment 1). HHS acknowledged that the request was received on March 14, 2023, and that it has been assigned FOI/PA number 2023-00557-FOIA-OS. (Attachment 2). Exela's request letter includes an application for expedited processing and outlines the reasons that expedited treatment of this request is warranted under 45 C.F.R. § 5.27 and 5 U.S.C. § 552(a)(6)(E).

To date, Exela has not received a determination in response to its request for expedited processing. 45 C.F.R. § 5.27(c) states that HHS will respond to requests for expedited processing "within 10 calendar days of [its] receipt of [the] request to expedite." *See also* 5 U.S.C. § 552(a)(6)(E)(ii) ("[N]otice of the determination [of whether to provide expedited processing] shall be provided to the person making the request, within 10 days after the date of the request."). This means that the statutory deadline for a response passed three weeks ago on March 24, 2023. Accordingly, we request that HHS immediately respond with a determination regarding Exela's request for expedited processing as statutorily required.

Separately, we received a letter from your office dated March 28, 2023, indicating that Exela "may wish to narrow the scope of [its] request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located." (Attachment 3). Without waiving, tolling, or resetting the FOIA statutory twenty-day (or thirty-day under "unusual circumstances") requirement for a response under 45 C.F.R. § 5.24 and 5 U.S.C. §§ 552(a)(6)(A) and (a)(6)(B), our client is willing to narrow the scope of the request to ensure HHS makes a determination and produces responsive records within the statutory time frame.

Accordingly, instead of requesting all records relating to Abbreviated New Drug Application ("ANDA") 213073, ANDA 214082, and ANDA 209994 regarding aluminum content, Exela is

willing to narrow its request to: correspondences, specifications, stability studies, and labeling discussions relating to ANDA 213073, ANDA 214082, and ANDA 209994 regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits) within HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or administrative unit of the Department, and/or any HHS employees), and the sponsor of ANDA 213073, ANDA 214082, and ANDA 209994 regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).

Additionally, Exela is willing to narrow the date range of its initial request (January 1, 2021 through the date of production) regarding ANDA 213073, ANDA 214082, and ANDA 209994, and suggests the following:

- ANDA 213073: Narrowed date range of June 1, 2022 through February 28, 2023.
- ANDA 214082: Narrowed date range of January 1, 2021 through May 31, 2022.
- ANDA 209994: Narrowed date range of January 1, 2020 through May 31, 2021.

Please confirm whether this would enable HHS to process Exela's March 14, 2023 FOIA request within the time frame mandated by FOIA. To reiterate, this proposal should not be construed as a request to create a new or separate FOIA request. Please confirm if you are amenable to narrowing the scope in this manner.

I welcome the opportunity to discuss this with you further and can be reached at jtorchinsky@holtzmanvogel.com.

Sincerely,

Jason Torchinsky
Holtzman Vogel Baran Torchinsky & Josefiak PLLC

Attachments

EXHIBIT 20

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00557-FOIA-OS

April 20, 2023

Sent via email:
Phanesh Koneru
Exela Pharma Sciences, LLC
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This is an interim response to your March 14, 2023, Freedom of Information Act (FOIA) request.

You requested the following: (1) any records relating to Abbreviated New Drug Application ("ANDA) 213073 ... regarding aluminum content...
2) any records relating to Abbreviated New Drug Application ("ANDA) 214082 ... regarding aluminum content...
any records relating to Abbreviated New Drug Application ("ANDA) 209994 ... regarding aluminum content... (Date Range for Record Search: From 1/1/2021 To 3/14/2023)).

HHS FOIA Office has determined your request for expedited processing does not meet the requirements under the FOIA and HHS implementing regulations and cannot be granted. The FOIA requires an agency expedite processing of a request only when the requester demonstrates a "compelling need."

Our review indicates you have not clearly demonstrated a "compelling need," because you have not clearly articulated an imminent threat to the life or physical safety of an individual; and you also have not demonstrated that there is an "urgency to inform the public concerning actual or alleged Federal activity" through a request by one primarily engaged in disseminating information to the public.

The law authorizes us to collect fees for responding to FOIA requests. However, because we are uncertain that applicable fees will exceed our minimum charge ($25.00), we are not addressing your request for a fee waiver at this time. Nevertheless, if we determine there will be fees associated with processing your request, we will contact you at that time.

The Department of Health and Human Services regulations allows us to recover part of the costs associated with the processing of FOIA requests. It was determined that your request will be processed under the "Commercial" category; therefore, your request may be subject to duplication fees at .10 cents per page after the first 100 pages of duplication. We will notify you if it appears that the fees will exceed the limit in which you set.

If you are not satisfied with my action on this request, you may administratively appeal this denial of expedited processing. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Please mark the correspondence, "Freedom of Information Act Appeal." Your appeal must be transmitted within 90 days from the date of receipt of this letter to:

William Holzerland
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
HHS.ACFO@hhs.gov

If you choose to mail your appeal, please clearly mark both the envelope and your letter "Freedom of Information Act Appeal." The mailing address is: Room 729H, 200 Independence Avenue, SW, Washington, DC 20201. Please note the entire office is working remotely and appeals sent by mail may receive delayed receipt dates.

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, you may contact the HHS FOIA Public Liaison for assistance at:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW, Suite 729H
Washington, DC 20201

Telephone: (202) 690-7453
Fax: (202) 690-8320
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001

Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

Sincerely yours

Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division

EXHIBIT 21

EXELA
PHARMA SCIENCES
1245 Blowing Rock Blvd
Lenoir, NC 28645
www.exelapharma.com

March 13, 2023

Arianne Perkins
Freedom of Information Officer
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Freedom of Information Act (FOIA) Request

Dear Freedom of Information Officer:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and HHS's FOIA implementing regulations, 45 C.F.R. § 5.21 *et seq*., Phanesh Koneru, Bridget Archer, and Exela Pharma Sciences, LLC (collectively "Requesters") hereby request the following records[1] in HHS's possession on or after January 1, 2021 through the date of production:

1. Congressional communications regarding aluminum content in cysteine drug products: All records containing or reflecting communications between HHS (including any Office, Division (other than the U.S. Food and Drug Administration ("FDA")[2]), or other administrative unit of the Department, and/or any HHS employees) and any member(s) of Congress, congressional committees or subcommittees, or congressional staff regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria, and/or aluminum limits) in cysteine hydrochloride ("cysteine") drug products.

[1] "Records," as that term is defined under FOIA (5 U.S.C. § 552(f)(2)), and under applicable case law (*see, e.g.*, *Forsham v. Harris*, 445 U.S. 169, 193 (1980)) include, but are not limited to, written correspondence, memoranda, records kept in electronic format on computers and/or electronic storage devices, email correspondence (whether through .gov email addresses or private third-party services such as Gmail), records of telephone correspondence, records pertaining to in-person meetings, calendar or scheduling entries, videotapes, photographs, computer print-outs, telephone messages, or voicemail messages.

[2] Requesters have filed separate FOIA requests directly with FDA and therefore do not need HHS to search FDA's records for responsive documents.

2. Other external communications regarding aluminum content in cysteine drug products: All records containing or reflecting communications between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees) and any non-governmental corporations, companies, partnerships, unincorporated associations, or other entities or individuals regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits) in cysteine drug products.

Requesters believe that responsive records are most likely to be located within HHS's Immediate Office of the Secretary, Office of the Assistant Secretary for Legislation, Office of the Assistant Secretary for Health, and Office of the General Counsel.

To facilitate your compliance with FOIA's 20-day deadline, *see* 5 U.S.C. § 552(a)(6)(A), Requesters ask that you begin by locating any responsive congressional communications (as detailed in #1 above) in the Immediate Office of the Secretary, Office of the Assistant Secretary for Legislation, and the Office of the General Counsel. Requesters further ask that you provide any responsive documents on a rolling basis, as soon as they are located and reviewed. Along with our outside counsel, Requesters would be pleased to discuss this request with you if doing so could help facilitate a timely response.

Finally, Requesters ask that HHS process this request consistent with the Department of Justice's policy memorandum (directed to the heads of executive departments and agencies) emphasizing the presumption of disclosure under FOIA, as amended by the FOIA Improvement Act of 2016.[3]

Request for Expedited Processing: Requesters further request that HHS provide expedited processing of this FOIA request. This request qualifies for expedited treatment pursuant to 45 C.F.R. § 5.27(b)(1) and 5 U.S.C. § 552(a)(6)(E) because the lack of publicly available information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of an individual," 5 U.S.C. § 552(a)(6)(E)(v)(I), including many preterm infants—whose lives depend on using these products, but who may be seriously harmed by exposure to unsafe levels of aluminum contamination in the process.[4]

L-cysteine is a necessity for proper human life functioning. While healthy adults can naturally synthesize small amounts of L-cysteine, certain high-risk patients—including preterm and/or low birth weight infants and patients with severe liver disease—require L-cysteine supplementation by parenteral administration. Aluminum toxicity in the administration of such treatment can cause serious health problems, including bone toxicity, dementia, impaired neurologic development, Alzheimer's disease, and liver disease, among other conditions. Federal regulation of aluminum

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[3] Dep't of Justice Office of Information Policy, Memorandum from The Attorney General, March 15, 2022, *available at* https://www.justice.gov/ag/page/file/1483516/download (last visited September 10, 2022).

[4] *See, e.g.*, Mark R. Corkins, "Review finds greatest risk of aluminum exposure is via parenteral nutrition," American Academy of Pediatrics News, Nov. 25, 2019, *available at* https://publications.aap.org/aapnews/news/13404 (last visited Mar. 6, 2023); Mark R. Corkins, Praveen S. Goday, and Ellen S. Rome, "Aluminum Effects in Infants and Children," American Academy of Pediatrics, vol. 144, no. 6 (Dec. 2019), *available at* https://publications.aap.org/pediatrics/article/144/6/e20193148/37901/Aluminum-Effects-in-Infants-and-Children?autologincheck=redirected (last visited Mar. 6, 2023); Heather A. Wier and Robert J. Kuhn, "Aluminum Toxicity in Neonatal Parenteral Nutrition: What Can We do?" SAGE Journals, vol 45, no. 1 (Jan. 2012), *available at* https://journals.sagepub.com/doi/10.1345/aph.1Q399 (last visited Mar. 6, 2023).

in these products thus has a direct impact on the health and safety of society's most vulnerable individuals, and the lack of publicly available information concerning aluminum levels in cysteine products "could reasonably be expected to pose an imminent threat to the life or physical safety," *id.*; 45 C.F.R. § 5.27(b)(1), by depriving healthcare professionals of critical information needed to ensure the health and safety of highly vulnerable patients, including preterm infants who require total parenteral nutrition ("TPN") and adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. Patients with underlying renal impairment who receive prolonged courses of parenteral nutrition support are at greatest risk of exposure to toxic levels of aluminum from parenteral nutrition. Obtaining the requested records regarding these government activities is necessary to protect the health of these vulnerable individuals.

As required by statute and federal regulation, the undersigned certify that the above information is true and correct to the best of their knowledge and belief.

Search and Processing of Requested Records: Upon receipt of this request, please take all reasonable steps to preserve relevant public records while the request is pending. Please also contact us promptly to provide an estimated date on which you will finish processing this request. Notice is hereby given that the Requester, requests an estimation of appropriate fees incurred and assessed for the "document search and duplication" of the department records responsive to this request if such fees should exceed $250.00. 5 U.S.C. § 552(a)(4)(A)(ii)(III).

Please search for responsive records regardless of format, medium, or physical characteristics. Requesters ask that responsive electronic records be produced electronically in their native file format, if possible, or the format most felicitous to an expedited production. Alternatively, Requesters request that the Records be provided electronically in text-searchable PDF, in the best image quality in HHS's possession, and in separate, Bates-stamped files.

If this FOIA request is denied in whole or in part, please provide the reasons for the denial, pursuant to 5 U.S.C. § 552(a)(6)(A)(i). If it is your position that any portion of the requested records is exempt from disclosure, we request that you provide a *Vaughn* index of those documents. *See Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973). As you are aware, a *Vaughn* index must describe each document claimed as exempt with sufficient specificity "to permit a reasoned judgment as to whether the material is actually exempt under FOIA." *Founding Church of Scientology v. Bell*, 603 F.2d 945, 959 (D.C. Cir. 1979). Moreover, the *Vaughn* index must "describe each document or portion thereof withheld, and for each withholding it must discuss the consequences of supplying the sought- after information." *King v. U.S. Dep't of Justice*, 830 F.2d 210, 223–24 (D.C. Cir. 1987).

In the event that some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable, non-exempt portions of the requested records. *See* 5 U.S.C. § 552(b). Pursuant to regulation, please clearly delineate any and all redactions in such a manner so that the justification for each redaction is apparent. If it is your position that a document contains non-exempt segments and that those non-exempt segments are so dispersed throughout the documents as to make segregation impossible, please state what portion of the document is non-exempt, and how the material is dispersed through the document. *Mead Data Cent. v. U.S. Dep't of the Air Force*, 455 F.2d 242, 261 (D.C. Cir. 1977). Claims of non-segregability must be

made with the same detail as required for claims of exemptions in a *Vaughn* index. If a request is denied in whole, please state specifically that it is not reasonable to segregate portions of the record for release.

For records available in electronic format, please email the documents to jtorchinsky@holtzmanvogel.com. Please send all other requested documents to the attention of:

Holtzman Vogel Baran Torchinsky & Josefiak
Attn: Jason Torchinsky
2300 N. St. NW Ste. 643A
Washington, D.C. 20037

Finally, we reiterate our request that responsive documents be made available as soon as they are located and reviewed *via* a rolling production. Requesters will pay reasonable increased costs incurred to facilitate a rolling production.

If you have any questions about this request, please do not hesitate to contact either me or my counsel.

Phanesh Koneru
Digitally signed by Phanesh Koneru
Date: 2023.03.13 12:04:40 -04'00'

Phanesh Koneru
Chief Executive Officer
(703) 964-7884
pkoneru@exela.us

Bridget Archer 3-13-2023

Bridget Archer
Pharmacist-in-Charge
(704) 301-7687
barcher@exela.us

EXHIBIT 22

Subject: Request Acknowledgement by U.S. Department of Health & Human Services

From: noreply@ains.com
Date: March 13, 2023 at 10:28:49 PM GMT+1
To: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>
Subject: Request Acknowledgement by U.S. Department of Health & Human Services

You don't often get email from noreply@ains.com. Learn why this is important

Dear Phanesh Koneru,

Your request has been received by the U.S. Department of Health & Human Services. The request has been assigned tracking # 2023-00555-FOIA-OS, please log into your account and review your submission.

The application address is https://requests.publiclink.hhs.gov.

Thank you,
U.S. Department of Health & Human Services

EXHIBIT 23

Subject: FW: HHS FOIA Clarification Letter -- 2023-00555-FOIA-OS
Attachments: HHS FOIA 1 -- Congressional and Third Party Communications.pdf; Clarification Letter.pdf

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From: Noussoukpoe, Ray <foiarequest@hhs.gov>
Sent: Tuesday, March 14, 2023 6:05 PM
To: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>
Subject: HHS FOIA Clarification Letter -- 2023-00555-FOIA-OS

Hello, Phanesh Koneru

Attached is a Clarification Letter to your FOIA request 2023-00555-FOIA-OS. If you have any questions, please contact HHS FOIA Office at FoiaRequest@hhs.gov.

Thank You

EXHIBIT 24

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00555-FOIA-OS

March 14, 2023

Sent via email:
Phanesh Koneru
Exela Pharma Sciences, LLC
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This clarification letter is in response to your March 13, 2023, Freedom of Information Act (FOIA) request. Specifically, you requested the following:

> ***"1. Congressional communications regarding aluminum content in cysteine drug products ...***
> ***2.Other external communications regarding aluminum content in cysteine drug products... (Date Range for Record Search: From 1/21/2021 To 3/13/2023)."***

The FOIA allows the public to request access to "reasonably described" existing agency records (subject to any applicable FOIA exemptions to disclosure). This means you must describe the category of records you are seeking or the actual document(s), and provide sufficient details to permit a search with reasonable effort, utilizing existing indices and search tools.

In accordance with Title 45 Code of Federal Regulations Subtitle A, Subpart B – How to Request Records under FOIA, HHS outlined what must be contained in FOIA requests to allow staff to locate requested records with a reasonable amount of effort. As set out in HHS FOIA Regulations,

> "….. a written description of the records you seek in sufficient detail to enable our staff to locate them with a reasonable amount of effort. The more information you provide, the better possibility we have of finding the records you are seeking. Information that will help us find the records would include:
>
> (1) The agencies, offices, or individuals involved;
> (2) The approximate date(s) when the records were created;
> (3) The subject, title, or description of the records sought; and
> (4) Author, recipient, case number, file designation, or other reference number, if available."

This letter is to obtain clarification regarding your FOIA request.
Unfortunately, you have not described the records with enough specificity to allow us to continue with the processing of your request. As stated in line one (1) name of all HHS

employees involved and any other individuals (**external to HHS if any**) involved name and email domain names are required.
In other words, **name of HHS employees and name and email domain names of all external individuals** who communicate "regarding aluminum content in cysteine drug products" are needed to conduct an electronic search for records.

Additionally, provide search key "terms" or "words" to use for an effective and efficient search.

The Office of the Chief Information Officer reports due to technology constraints, HHS cannot run a blind search against all users in HHS or an operating/staff division. Electronic searches run against our live email system and a search against all HHS employees would crash our system.

Regarding the search terms, we would need the domain names for each entity in the list so that we could identify emails to or from a custodian to those entities. For example, "emails to or from Jane Doe (Jane.Doe@hhs.gov) and @organization.org or @commercial_entity.com" with specific key words and date ranges.

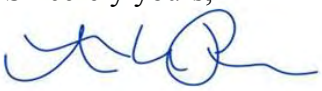
Once you provide the above information/details clarifying you request, we can conduct a search.

At this time, we have placed your request in "tolled" status. Therefore, please clarify and describe the records you are seeking, by sending an email to Ray Noussoukpoe, of my staff, at FOIARequest@hhs.gov.

After you further advise us what records you are seeking, we can begin to process your FOIA request.

HHS "may deny your request for other reasons, including that a request does not reasonably describe the records sought" in accordance with the HHS FOIA Regulations cited in paragraph three. If you have not contacted our office within 30 business days from the date of this letter, your request will be administratively closed. Therefore, no action on your part is needed, if you no longer have a need for the records.

Sincerely yours,



Arianne Perkins
Director
FOI/Privacy Acts Division

EXHIBIT 25

EXELA
PHARMA SCIENCES
1245 Blowing Rock Blvd
Lenoir, NC 28645
www.exelapharma.com

March 19, 2023

Arianne Perkins
Freedom of Information Officer
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Case No. 2023-00555-FOIA-OS

Ms. Perkins:

I write in response to your March 14, 2023 letter (the "Clarification Letter") requesting additional information with respect to the above-captioned FOIA request (the "Request"). As you know, that Request sought:

1. Congressional communications regarding aluminum content in cysteine drug products: All records containing or reflecting communications between HHS (including any Office, Division (other than the U.S. Food and Drug Administration ("FDA")[1]), or other administrative unit of the Department, and/or any HHS employees) and any member(s) of Congress, congressional committees or subcommittees, or congressional staff regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria, and/or aluminum limits) in cysteine hydrochloride ("cysteine") drug products.

2. Other external communications regarding aluminum content in cysteine drug products: All records containing or reflecting communications between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees) and any non-governmental corporations, companies, partnerships, unincorporated associations, or other entities or individuals regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits) in cysteine drug products.

[1] As the Request's original footnote 1 noted, "Requesters have filed separate FOIA requests directly with FDA and therefore do not need HHS to search FDA's records for responsive documents."

Request at 1 & n.1. In an effort to facilitate your compliance with FOIA, the Request further observed "that responsive records are most likely to be located within HHS's Immediate Office of the Secretary, Office of the Assistant Secretary for Legislation, Office of the Assistant Secretary for Health, and Office of the General Counsel," *id.* at 2, and specifically asked "that you begin by locating any responsive [records] in the Immediate Office of the Secretary, Office of the Assistant Secretary for Legislation, and the Office of the General Counsel." *Id.*

Despite the specificity of our Request—which, generally speaking, seeks all records regarding communications between HHS and outside parties regarding aluminum content in cysteine drug products—the Clarification Letter asserts that the Request did "not describe[] the records with enough specificity" simply because it did not provide the "name of all HHS employees involved and any other individuals (**external to HHS if any**) involved name and email domains are required." Clarification Ltr. at 1-2 (all emphases as in original). The Clarification Letter further suggests that HHS's FOIA regulations ***require*** us to provide this information as a condition of processing the Request. *Id.* at 1 ("In accordance with Title 45 Code of Federal Regulations Subtitle A, Subpart B – How to Request Records under FOIA, HHS outlined what must be contained in FOIA requests to allow staff to locate requested records with a reasonable amount of effort.").

Those assertions are incorrect: The cited regulation does not remotely require FOIA requesters to identify each (or any) of the particular individuals who may have been involved in creating certain responsive records (whether as an author or recipient) or to supply any of the additional information you have demanded.[2] Instead, the cited regulation merely identifies certain kinds of "[i]nformation ***that will help us*** find the records you are seeking" and then lists as, illustrative examples, "the agencies, offices, ***or*** individuals involved" and the "author, recipient, case number, file designation, or other reference number, ***if available.***" 45 C.F.R. § 5.22(a)(1), (4) (both emphases added). The Clarification Letter's assertion that this regulation somehow "require[s]" Requesters to provide the information you have demanded therefore is triply flawed.

First, the courts have held that substantially similar FOIA regulations—which merely identify useful categories of information that would be helpful to the processing federal agency—do ***not*** in fact require FOIA requesters to supply all (or indeed any) such information as a condition of processing a FOIA request. *See, e.g., Biear v. Attorney General of the United States*, 905 F.3d 151, 156 (3d Cir. 2018) ("The government contends that Biear's request was insufficiently detailed, in part because it failed to suggest specific sections [of the Department of Justice] in which responsive records might be maintained. The text of the regulation does not require that a request contain that information. It states only that a request should contain that information '[t]o the extent possible.'") (discussing 28 C.F.R. § 16.3(b) ("Requesters must describe the records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount

[2] We note that the only concerns your response articulates relate to email searches. Clarification Letter at 2 (demanding that Requesters provide "email domain names"); *id.* (complaining that "HHS cannot run a blind search against all users in HHS or an operating/staff division" because "our live email system … would crash"); *id.* (seeking domain name information "so that we could identify emails to or from a custodian to those entities"). But the Request is not limited to emails; it seeks "***All records*** containing or reflecting communications" between HHS and outside parties regarding the specified subject matter, Request at 1 (emphasis added)—some of which may be contained in emails, and some of which may be contained in other Department records. *Id.* at 1 n.1 (defining the term "records"). You therefore have provided no basis for refusing to commence a search of your other systems for responsive records, and Requesters accordingly reject the Clarification Letter's assertion that the deadline for responding to this Request has been, or legitimately can be, "tolled." *Cf.* Clarification Letter at 2.

of effort. To the extent possible, requesters should include specific information that may assist a component in identifying the requested records, such as the date, title or name, author, recipient, subject matter of the record, case number, file designation, or reference number.")). HHS's regulation does not differ materially from the Department of Justice's: Just like DOJ's regulation, HHS's regulation begins by asserting that FOIA requesters must describe "the records you seek in sufficient detail to enable our staff to locate them with a reasonable amount of effort," and then identifies certain categories of "information that will help us … if available." 45 C.F.R. § 5.22(a). It does not, however, ***require*** FOIA requesters to supply any such information (whether available or not) as a condition of fulfilling the request, just as the courts have made clear that DOJ's substantially similar regulation includes no such requirement. *See Biear*, 905 F.3d at 156.

Second, the Request fully complied with your regulation in any event. Whether or not the regulation requires Requesters to supply certain categories of information (and it doesn't, for the reasons we have just explained), the Request did exactly what the regulation expressly authorizes: It specifically identified "the agencies, offices, ***or*** individuals involved," 45 C.F.R. § 5.22(a) (emphasis added), by noting "that responsive records are most likely to be located within HHS's Immediate Office of the Secretary, Office of the Assistant Secretary for Legislation, Office of the Assistant Secretary for Health, and Office of the General Counsel," Request at 1, and then asking you to prioritize searches "in the Immediate Office of the Secretary, Office of the Assistant Secretary for Legislation, and the Office of the General Counsel." *Id.* at 1. Needless to say, each of the identified "Office[s]" is an "office" within the meaning of 45 C.F.R. § 5.22(a). And the regulation's disjunctive use of the word "***or***" makes clear that FOIA requesters are ***not*** required to supply the names of all "agencies, offices, ***and*** individuals involved" (assuming, for the sake of argument, that it requires anything at all). Any one of those alternatives suffices, and the Request supplied them. *See, e.g.*, *In re Espy*, 80 F.3d 501, 505 (D.C. Cir. 1996) ("[A] statute written in the disjunctive is generally construed as setting out separate and distinct alternatives."); *cf. Loving v. IRS*, 742 F.3d 1013, 1019 (D.C. Cir. 2014) ("[T]he statute uses the conjunctive 'and' — not the disjunctive 'or' — when listing the various requirements, a strong indication that Congress did not intend the requirements as alternatives.").

Finally, the cited regulation expressly acknowledges that FOIA requesters may not have the information you are demanding Requesters now provide—here, for instance, the names and email addresses of any and all persons involved in communications that are contained or reflected in the records we have requested—and therefore makes clear that such information can only "help [HHS]" (let alone be required as a condition of processing a given FOIA request) "***if available***." 45 C.F.R. § 5.22(a)(4) (emphasis added). That commonsense recognition precisely describes this matter. By its plain terms, the Request seeks information about communications to which Exela was not a party. Requesters do not know, and cannot know, every single person at HHS who may have had communications about the Request's subject matter with outside parties, let alone every single person outside of HHS who may have had communications with HHS about that subject matter. Indeed, the whole point of the Request is to determine ***whether*** there were such communications, ***who*** was involved in such communications, and ***what*** those communications were. FOIA in turn makes it your responsibility to find that information for us—not force us to divine and disclose the unknowable as a condition of complying with your statutory obligations.

That having been said, Requesters certainly understand that compliance with your FOIA obligations may require you to run a variety of email searches given the alleged limitations of your

email system (though we note that is a problem for which Requesters assuredly are not responsible, and which does not otherwise justify HHS's refusal to process the Request). HHS of course maintains names and contact information for **all** staff within the identified Offices (*e.g.*, the Immediate Office of the Secretary, Office of the Assistant Secretary for Legislation, Office of the Assistant Secretary for Health, and Office of the General Counsel). And Requesters have no objection to you running individual searches for responsive documents on an employee-by-employee basis if it really is true that your email system is incapable of running searches on a broader basis (again, however, we note that your own FOIA regulation expressly provides that requests can be made, and therefore can he processed, on an agency- or office-wide basis, and not merely on an individual-by-individual basis, *see* 45 C.F.R. § 5.22(a)(1)).

To the extent it would further assist your efforts, ***and without limiting the scope of the Request in any way***, we might suggest your search of emails begin with the following HHS custodians:

1. Xavier Becerra – Xavier.Becerra@hhs.gov
2. Sean McCluskie – Sean.Mccluskie@hhs.gov
3. Angela Ramirez – Angela.Ramirez@hhs.gov
4. Anne Reid – Anne.Reid@fda.hhs.gov
5. Stephen Cha – Stephen.Cha@hhs.gov
6. Karuna Seshasai – Karuna.Seshasai@hhs.gov
7. Elizabeth Gramling – Elizabeth.Gramling@hhs.gov
8. Kashif Syed – TauheedAliKashif.Syed@hrsa.hhs.gov
9. Samuel Bagenstos – Samuel.Bagenstos@hhs.gov
10. Andrea Palm – Andrea.Palm@hhs.gov
11. Angela Botticella – Angela.Botticella@hhs.gov
12. Melanie Egorin – Melanie.Egorin@hhs.gov
13. Rose Sullivan – Rose.Sullivan@hhs.gov
14. Madeline Daly - Madeline.Daly@hhs.gov
15. Kimberly Espinosa - Kimberly.Espinosa@hhs.gov
16. Alex Graf - Alex.Graf@hhs.gov
17. Steven "Jeff" Hild - Jeff.Hild@acf.hhs.gov
18. Peter Rechter – Peter.Rechter@hhs.gov
19. Leslie Zelenko – Leslie.Zelenko@hhs.gov
20. Staceye Arrington – Staceye.Arrington@hhs.gov
21. William Brady – William.Brady@hhs.gov
22. Caitlin Fross – Caitlin.Fross@hhs.gov
23. Syed Mohiuddin – Syed.Mohiuddin @hhs.gov
24. Remi Roberts – Remi.Roberts@hhs.gov
25. Adm. Rachel L. Levine, MD – Rachel.Levine@hhs.gov
26. Sarah Boateng – Sarah.Boateng@hhs.gov
27. Maura Calsyn – Maura.Calsyn@hhs.gov
28. Michael Iademarco – Michael.Iademarco@hhs.gov
29. Mirabelle Adamu – Mirabelle.Adamu@hhs.gov
30. Evan Sturtevant – Evan.Sturtevant@hhs.gov
31. Steven Rush – Steven.Rush@hhs.gov
32. Keian Weld – Keian.Weld1@hhs.gov
33. HHS Counselors – HHS.Counselors@hhs.gov

Please also request that any custodians review personal email addresses for responsive documents.

We also are pleased to provide the following key search terms to help facilitate your identification of records—whether contained in emails or otherwise—that may be responsive to the Request: "aluminum," "cysteine," "Nivagen," "Sandoz," "Eton," "Exela," "small volume parenteral," and/or "SVP."

Finally, and as the Request previously noted, Requesters ask that responsive documents be made available as soon as they are located and reviewed *via* a rolling production—a request that is all the more important given that your Clarification Letter raises concerns ***only*** with respect to HHS's search of email-based records, and ***not*** any of the other types of records that might be responsive to the Request. To the extent you continue to have concerns about the email component of the Request after considering this correspondence, we reiterate that there is no lawful basis for refusing to search your other systems/locations for responsive documents and remind you of HHS's statutory obligation to respond to the Request within 20 days. 5 U.S.C. § 552(a)(6)(A).

If you have further questions about this request, we respectfully suggest that a telephone conference with me and my outside counsel might be the most efficient course of action. Please let me know if and when you would like discuss these issues.

Phanesh Koneru Digitally signed by Phanesh Koneru Date: 2023.03.19 23:35:47 -04'00'

Phanesh Koneru
Chief Executive Officer
(703) 964-7884
pkoneru@exela.us

Bridget Archer 3-19-2023

Bridget Archer
Pharmacist-in-Charge
(704) 301-7687
barcher@exela.us

EXHIBIT 26

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Refer to: Request Number **2023-00555-FOIA-OS**

March 28, 2023

Sent via email:
Phanesh Koneru
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This acknowledges receipt of your March 13, 2023, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning **"1. Congressional communications regarding aluminum content in cysteine drug products ...**
2.Other external communications regarding aluminum content in cysteine drug products... (Date Range for Record Search: From 1/21/2021 To 3/13/2023)".
We received your request on March 13, 2023.

Because you seek records which require a search in another office, "unusual circumstances" apply to your request, automatically extending the time limit to respond to your request for ten additional days. See 5 U.S.C. 552 § (a)(6)(B)(i)-(iii) (2012 & Supp. V. 2017). Further, we estimate needing more than 10 additional days to respond to your request and so, in the next paragraph of this letter we are offering you an opportunity to narrow your request, in case narrowing the request would enable us to respond to the request sooner. The actual time needed to process your request will depend on the complexity of our records search and on the volume and complexity of any material located. For your information, this Office assigns incoming requests to one of three tracks: simple, complex, or expedited. Each request is then handled on a first-in, first-out basis in relation to other requests in the same track. Our current workload is approximately 3000 cases.

Your request is assigned to the complex track. In an effort to speed up our records search, you may wish to narrow the scope of your request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located. You may also wish to await the completion of our records search to discuss either of these options.

I regret the necessity of this delay, but I assure you that your request will be processed as soon as possible. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Ray Noussoukpoe at FoiaRequest@PSC.hhs.gov.

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)

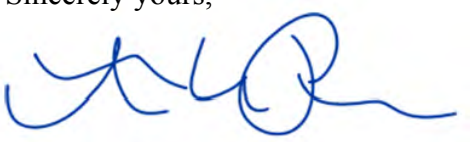
Telephone: (202) 690-7453
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

and/or:

Office of Government Information Services
National Archives and Records Administration
Telephone: 202- 741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

If you are not already submitting your requests through our Public Access Link (PAL), we recommend all future requests and appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting requests through PAL automatically logs your requests into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your request, receive your documents directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

Sincerely yours,



Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division

EXHIBIT 27

From: Noussoukpoe, Ray <foiarequest@hhs.gov>
Sent: Tuesday, March 28, 2023 12:34 PM
To: jtorchinsky@holtzmanvogel.com
Subject: HHS FOIA Acknowledgement Letter -- 2023-00555-FOIA-OS

Dear Phanesh Koneru

Please see the attached Acknowledgement Letter in response to your FOIA Request submitted to the Department of Health and Human Services (HHS) via E-mail on March 13, 2023.
The letter contains important information concerning your FOIA matter which has been assigned tracking number **2023-00555-FOIA-OS**.
For status updates or other inquiries, please contact our office via email at FOIARequest@hhs.gov. *Please include your tracking number in the subject line of your inquiry,*

Sincerely,

HHS FOIA Office

EXHIBIT 28

From: noreply@ains.com
Date: March 28, 2023 at 12:41:56 PM EDT
To: Jason Torchinsky <jtorchinsky@holtzmanvogel.com>
Subject: Status Update for Request #2023-00555-FOIA-OS

Dear Phanesh Koneru,

The status of your FOIA request #2023-00555-FOIA-OS has been updated to the following status 'In Process'. To log into the HHS FOIA Submission Site click on the Application URL below.

https://requests.publiclink.hhs.gov

Sincerely,
U.S. Department of Health & Human Services

EXHIBIT 29

Holtzman Vogel

HOLTZMAN VOGEL BARAN TORCHINSKY & JOSEFIAK PLLC

April 18, 2023

Arianne Perkins
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

RE: STATUS OF REQUEST FOR EXPEDITED PROCESSING AND NARROWING SCOPE OF REQUEST (FOI/PA Request No. 2023-00555-FOIA-OS)

Ms. Perkins,

On March 13, 2023, my client, Exela Pharma Sciences, LLC ("Exela"), through its Chief Executive Officer, Phanesh Koneru, and Pharmacist-In-Charge, Bridget Archer, submitted a request for records from HHS under the Freedom of Information Act ("FOIA"). 5 U.S.C. § 552; 45 C.F.R. § 5.21. (Attachment 1). HHS acknowledged that the request was received on March 13, 2023, and that it has been assigned FOI/PA number 2023-00555-FOIA-OS. (Attachment 2). Exela's request letter includes an application for expedited processing and outlines the reasons that expedited treatment of this request is warranted under 45 C.F.R. § 5.27 and 5 U.S.C. § 552(a)(6)(E).

To date, Exela has not received a determination in response to its request for expedited processing. 45 C.F.R. § 5.27(c) states that HHS will respond to requests for expedited processing "within 10 calendar days of [its] receipt of [the] request to expedite." *See also* 5 U.S.C. § 552(a)(6)(E)(ii) ("[N]otice of the determination [of whether to provide expedited processing] shall be provided to the person making the request, within 10 days after the date of the request."). This means that the statutory deadline for a response passed three weeks ago on March 23, 2023. Accordingly, we request that HHS immediately respond with a determination regarding Exela's request for expedited processing as statutorily required.

Separately, we received a letter from your office dated March 28, 2023 indicating that Exela "may wish to narrow the scope of [its] request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located." (Attachment 3). Without waiving, tolling, or resetting the FOIA statutory twenty-day (or thirty-day under "unusual circumstances") requirement for a response under 45 C.F.R. § 5.24 and 5 U.S.C. §§ 552(a)(6)(A) and (a)(6)(B), our client is willing to narrow the scope of the request to ensure HHS makes a determination and produces responsive records within the statutory time frame.

Accordingly, instead of the original date range of January 1, 2021 through the date of production, we propose a narrowed date range of December 1, 2021 through the date of production.

Please confirm whether this would enable HHS to process Exela's March 13, 2023 FOIA request within the time frame mandated by FOIA. To reiterate, this proposal should not be construed as a request to create a new or separate FOIA request. Please confirm if you are amenable to narrowing the scope in this manner.

I welcome the opportunity to discuss this with you further and can be reached at jtorchinsky@holtzmanvogel.com.

Sincerely,

Jason Torchinsky
Holtzman Vogel Baran Torchinsky & Josefiak PLLC

Attachments

EXHIBIT 30

DEPARTMENT OF HEALTH & HUMAN SERVICES
Secretary

Office of the

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00555-FOIA-OS

April 20, 2023

Sent via email:
Phanesh Koneru
Exela Pharma Sciences, LLC
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This is an interim response to your March 14, 2023, Freedom of Information Act (FOIA) request.

You requested the following: (All records relating to development, drafting, and/or publication of the December Draft Guidance titled Small volume parenteral drug products and pharmacy bulk packages for parenteral nutrition: Aluminum content and labeling recommendations ... (Date Range for Record Search: From 1/1/2021 To 3/14/2023)).

HHS FOIA Office has determined your request for expedited processing does not meet the requirements under the FOIA and HHS implementing regulations and cannot be granted. The FOIA requires an agency expedite processing of a request only when the requester demonstrates a "compelling need."

Our review indicates you have not clearly demonstrated a "compelling need," because you have not clearly articulated an imminent threat to the life or physical safety of an individual; and you also have not demonstrated that there is an "urgency to inform the public concerning actual or alleged Federal activity" through a request by one primarily engaged in disseminating information to the public.

The law authorizes us to collect fees for responding to FOIA requests. However, because we are uncertain that applicable fees will exceed our minimum charge ($25.00), we are not addressing your request for a fee waiver at this time. Nevertheless, if we determine there will be fees associated with processing your request, we will contact you at that time.

The Department of Health and Human Services regulations allows us to recover part of the costs associated with the processing of FOIA requests. It was determined that your request will be processed under the "Commercial" category; therefore, your request may be subject to duplication fees at .10 cents per page after the first 100 pages of duplication. We will notify you if it appears that the fees will exceed the limit in which you set.

If you are not satisfied with my action on this request, you may administratively appeal this denial of expedited processing. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Please mark the correspondence, "Freedom of Information Act Appeal." Your appeal must be transmitted within 90 days from the date of receipt of this letter to:

William Holzerland
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
HHS.ACFO@hhs.gov

If you choose to mail your appeal, please clearly mark both the envelope and your letter "Freedom of Information Act Appeal." The mailing address is: Room 729H, 200 Independence Avenue, SW, Washington, DC 20201. Please note the entire office is working remotely and appeals sent by mail may receive delayed receipt dates.

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, you may contact the HHS FOIA Public Liaison for assistance at:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW, Suite 729H
Washington, DC 20201

Telephone: (202) 690-7453
Fax: (202) 690-8320
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001

Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

Sincerely yours,

Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division