



April 21, 2023

Submitted online at <https://requests.publiclink.hhs.gov/>

U.S. Department of Health and Human Services
Freedom of Information Act Office
Hubert H. Humphrey Building., Room 729H
200 Independence Avenue, SW
Washington, DC 20201

Re: Communications with 22nd Century, Inc. and key officials

Dear Freedom of Information Act Officer:

The Functional Government Initiative (FGI) submits this request for records under the Freedom of Information Act, 5 U.S.C. § 552, as amended (FOIA), and the relevant implementing regulations. FGI, a non-partisan organization, engages in research, investigation, and education to promote transparency in government. Your prompt response pursuant to the requirements of FOIA, 5 U.S.C. § 522(a)(6)(A), is appreciated.

On June 1, 2022, the Biden-Harris Administration published its plans for future regulatory actions against tobacco and nicotine products.¹ This plan includes a recommendation to the FDA to establish a maximum nicotine level for electronic cigarette and tobacco products. The goal for establishing such regulation is to reduce the likelihood of long-term addiction, particularly for underage consumers.

In December 2021, the FDA announced it had authorized the marketing of two brands of combusted, filtered cigarettes as modified risk tobacco products (MRTPs). The FDA stated, “These are the first combusted cigarettes to be authorized as MRTPs and the second tobacco products overall to receive ‘exposure modification’ orders, which allows them to be marketed as having a reduced level of, or presenting a reduced exposure to, a substance.”² Two years earlier, FDA had authorized the marketing and sale of two new “reduced nicotine” tobacco products.³ All of these products are manufactured by a single company, 22nd Century Group, Inc. The public should know whether the company was communicating directly with key officials and, if so, what was discussed about regulations that may lead to a monopoly.

¹ <https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco>

² <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-tobacco-products-help-reduce-exposure-and-consumption-nicotine-smokers-who>

³ <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-two-new-reduced-nicotine-cigarettes-through-premarket-tobacco-product-application>

REQUESTED RECORDS

FGI requests all records between the custodians identified and anyone with 22nd Century Group. The date range is January 21, 2021, through December 23, 2021.

This would include the following people with the company:

- James A. Mish, CEO (Jmish@xxiicentury.com)
- Calvin Treat, Chief Scientific Officer (Ctreat@xxiicentury.com)
- John Miller, President, Tobacco Business (JMiller@xxiicentury.com)
- John D. Pritchard, Vice President of Regulatory Science (JPritchard@xxiicentury.com)
- Juan Sanchez Tamburrino, Vice President of Research and Development (JTamburrino@xxiicentury.com)
- Peter Ferola, Chief Legal Officer (PFerola@xxiicentury.com)
- Lindsay Castro, Associate Corporate Counsel (LCastro@xxiicentury.com)
- Shiva Vellanki, Vice President - US Federal Business Practices (SVellanki@xxiicentury.com)
- Eric Cheney, Communications Manager (Echeney@xxiicentury.com)
- Brittainy Dye, Regulatory Compliance Manager (BDye@xxiicentury.com)
- Anyone else with an email ending with @xxiicentury.com

Custodians:

- Andrea Palm, Deputy Secretary
- Angela Botticella, Chief of Staff, Office of the Deputy Secretary
- Other staff in the immediate office of the Deputy Secretary
- The Assistant Secretary for Public Affairs
- Anyone in the office of the Assistant Secretary for Public Affairs who works on the Public Health team within the office

The term “all records” in this request refers to emails including attachments, text messages (including messages on encrypted apps such as Signal or WhatsApp), calendars, electronic meeting invitations and replies, letters, correspondence, facsimiles, memoranda, notes from meetings and phone calls, minutes of meetings, agendas of meetings, comments, files, presentations, consultations, drawings, diagrams, graphs, charts, assessments, evaluations, telephone records and logs, virtual meeting logs (such as those produced by Microsoft Teams and Zoom), papers (published or unpublished), reports, studies, photographs and other images, databases, data, maps, or all other responsive records in draft or final form that fall within the definition of “agency records” subject to FOIA. This request is not meant to exclude any other records that, although not specifically requested, are reasonably related to the subject matter of this request.

We ask that you please provide all records in an electronic format and, to the extent practicable, in native file format or, if not practicable, with full metadata for all fields. FOIA provides that “an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the agency in that form or format.”⁴ Please provide records in either a load-ready format with an index in .csv file or Excel spreadsheet, or in PDF format without any portfolios or embedded files and not in a single batched pdf file.

If you should seek to withhold or redact any responsive records, we request that you do the

⁴ 5 U.S.C. § 552(a)(3)(B).

following:

1. Identify each such record with specificity, including date, author, recipient, and parties copied,
2. Explain in full the basis for withholding responsive material,
3. Provide all segregable portions of the records for which you claim a specific exemption⁵, and
4. Correlate any redactions with specific exemptions under FOIA.

If you or your office have destroyed or decide to withhold any records that could be reasonably construed to be responsive to this request, we ask that you indicate this fact and the reasons for doing so in your response. Agencies are prohibited from denying requests for information under FOIA unless the agency reasonably believes release of the information will harm an interest that is protected by the exemption.⁶

Should you decide to invoke a FOIA exemption or any subsection (c) exclusions, please include sufficient information for us to assess the basis for the exemption, including any interests that would be harmed by release. Please include a detailed ledger with the following:

1. Basic factual material about each withheld record, including the originator, date, length, general subject matter, and location of each item, and
2. Complete justifications for each withheld records, including the specific exemptions under which the record or portion thereof, was withheld and a full explanation of how each exemption applies to the withheld material. Such statements will be helpful in deciding whether to appeal an adverse determination. Your written justification may help to avoid litigation.

If you determine that portions of the records requested are exempt from disclosure, we request that you segregate the exempt portions and send the non-exempt portions to my email address below within the statutory time limit.⁷

FGI is willing to receive records on a rolling basis.

To facilitate our request most efficiently, we request that the FOIA office use the agency's email management system as part of the search for this request.

REQUEST FOR FEE WAIVER

Pursuant to 5 U.S.C. § 552 and the relevant FOIA regulations, we request a waiver of fees for searching and producing the records of this request. FOIA provides for a waiver of fees when a request is "in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester."⁸

Below are details explaining (1) how the disclosure of the requested records is in the public

⁵ See 5 U.S.C. § 552(b).

⁶ FOIA Improvement Act of 2016 (Public Law No. 114-185), 5 U.S.C. § 552(a)(8)(A).

⁷ 5 U.S.C. § 552(b).

⁸ 5 U.S.C. § 552(a)(4)(A)(iii).

interest, (2) that FGI intends distribute information to a broad audience of interested persons, and (3) that FGI has no commercial interests.

In addition, FGI is a “person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience” and thus qualifies as a “representative of the news media” under 5 U.S.C. § 552(a)(4)(A)(ii). Below are details explaining (4) how FGI clearly meets these criteria.

1. THE REQUEST IS IN THE PUBLIC INTEREST.

Under FOIA, an agency must consider factors to determine whether a request is in the public interest. These include the following:

- A. Whether the subject of the requested records concerns “the operations or activities of the Federal government,”
- B. Whether the disclosure is “likely to contribute significantly” to an understanding of government operations or activities, and
- C. Whether the disclosure “will contribute to public understanding” of a reasonably broad audience of persons interested in the subject.

As shown below, FGI meets each of these factors.

A. The requested records concern the operations and activities of the Federal government.

This request seeks communications between a company regulated by the FDA, part of HHS, and HHS officials. The Department of Justice Freedom of Information Act Guide acknowledges that “in most cases records possessed by a federal agency will meet this threshold.”⁹ The threshold is met here not only because the records sought are by nature possessed by agency staff but also because they relate to work of the federal government.

Thus, FGI meets this factor.

B. Disclosure is “likely to contribute significantly” to an understanding of government operations or activities.

Disclosure of the requested records is certain to contribute significantly to public understanding of the HHS. Knowing whether and, if so, what key officials are communicating with the only company to so far have its low nicotine products approved will certainly shed light on the government’s work. Once the information is made available, FGI will evaluate the information and present it to its followers and make it available to the public.

FGI is not requesting these records merely for their intrinsic informational value. The public is always well served when it knows details of what officials are communicating with interest groups. Hence, there can be no dispute that disclosure of the requested records to the public will significantly increasing the public’s understanding about the agency’s actions and whether those actions were conducted in an objective, ethical, and legal way. Thus, FGI meets this factor.

C. Disclosure of the requested records will contribute to the understanding of a reasonably

⁹ <https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/fees-feewaivers.pdf>

broad audience.

FGI has the ability and intention to convey this information to a broad audience (by means discussed in Section 2 below). The public does not currently have an ability to evaluate the requested records. With the wide reach of the FDA's regulatory power and the impact of its work in many different areas, a very broad audience interested in government transparency, public health policy, and ethics compliance, among other issues, would achieve a greater understanding of their government's work from the requested records.

Such public oversight of agency action is vital to our democratic system and clearly envisioned by the drafters of the FOIA. Thus, FGI meets this factor.

2. FGI HAS THE ABILITY AND INTENT TO DISSEMINATE THE INFORMATION TO A REASONABLY BROAD AUDIENCE INTERESTED IN THE SUBJECT.

FGI is a non-partisan organization that researches government operations and informs the public its findings. Access to information about the activities and decisions of government officials is vital to fulfilling this mission. Once the information is obtained, FGI has robust mechanisms in place, including its website, social media channels, and other platforms, to share information. FGI intends to use its channels to publish the information from these requested records, along with expert analysis. FGI also has a broad network of reporters, bloggers, and media publications with interest in its content and with durable relationships with the organization. FGI intends to use these far-reaching media outlets to publicize information obtained from this request.

Through these means, FGI's dissemination of the information will:

- Ensure that the information requested contributes significantly to the public's understanding of the government's operations or activities,
- Ensure that the information enhances the public's understanding to a greater degree than currently exists,
- Demonstrate that FGI possesses the expertise to explain the requested information to the public,
- Demonstrate that FGI possesses the ability to make the requested information accessible to the general public, and
- Demonstrate that the news media recognizes FGI as a reliable source in the relevant field.

In determining whether disclosure of requested information will contribute significantly to public understanding, a guiding test is whether the requester will disseminate the information to a reasonably broad audience of persons interested in the subject.¹⁰ FGI need not show how it intends to distribute the information, because, as the court noted, "nothing in FOIA, the [agency] regulation, or our case law require[s] such pointless specificity."¹¹ It is sufficient for FGI to show how it distributes information to the public generally.¹²

3. OBTAINING THE REQUESTED RECORDS IS OF NO COMMERCIAL INTEREST TO FGI.

Disclosure is in no way connected with any commercial interest of the requestors. FGI is a non-

¹⁰ *Carney v U.S. Dept. of Justice*, 19 F.3d 807 (2nd Cir. 1994).

¹¹ *Judicial Watch*, 326 F.3d at 1314.

¹² *Id.*

partisan organization. FGI has no commercial interest and will realize no commercial benefit from the release of the requested records.

4. FGI IS A REPRESENTATIVE OF THE NEWS MEDIA.

Under FOIA, the term “representative of the news media” includes any person or entity that “gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience.”¹³ In *Cause of Action v. Federal Trade Commission*, the Court of Appeals for the District of Columbia broke the test for who is a media entity into five parts: “A requester must: (1) gather information of potential interest (2) to a segment of the public; (3) use its editorial skills to turn the raw materials into a distinct work; and (4) distribute that work (5) to an audience.”^{14 15}

In interpreting this test, the court noted “the news-media waiver . . . focuses on the nature of the requester, not its request.”¹⁶ Accordingly, where a requester “satisfies the five criteria as a general matter, it does not matter whether any of the individual FOIA requests does so.”¹⁷ Moreover, the media entity waiver applies to newer organizations as well as older ones: “there is no indication that Congress meant to make the lack of a prior publication record disqualifying when it enacted the statutory definition in 2007.”¹⁸

A. FGI gathers information of potential interest.

FGI’s mission is to demand transparency and promote shared values and beliefs in a thriving economy, a healthy America, a strong and equitable workforce, and a safe and clean environment. As part of this mission, FGI engages in investigations and education initiatives around important issues, including high energy prices, the government’s COVID-19 response, and government transparency. These are topics of potentially broad public interest, as evidenced by the fact that multiple news outlets have written stories on FGI’s work. You can see several FGI’s media mentions at <https://functionalgovernment.org/category/media-mentions/>.

B. FGI gathers information of interest to a segment of the public.

As demonstrated above, the information that FGI gathers is of interest to a segment of the public. This includes but is not limited to the segment of the public concerned with government transparency. The size of the segment of the public interests in any particularly information gathering project may vary, however, as the court has noted, “[a] newspaper reporter, for example, is a representative of the news media regardless of how much interest there is in the story for which he or she is requesting information.”¹⁹ Moreover, as long as FGI “satisfies the five criteria as a general matter, it does not matter whether any of the individual FOIA requests does so.”²⁰

¹³ 5 U.S.C. § 552(a)(4)(A)(ii).

¹⁴ 799 F.3d 1108, 1120 (D.C. Cir. 2015).

¹⁵ The court further noted that “the news-media fee waiver applies only to records that ‘are not sought for commercial use.’” *Cause of Action*, 700 F.3d at 1120. For the reasons set forth in section 3 above, FGI is not requesting these records for commercial use.

¹⁶ 799 F.3d 1108, 1120 (D.C. Cir. 2015) at 1121 (emphasis in the original).

¹⁷ *Id.*

¹⁸ *Id.* at 1124.

¹⁹ *Cause of Action*, 799 F.3d at 1121.

²⁰ *Id.*

As set forth above, FGI believes that this request is of interest to a reasonably broad segment of the public. Even if the agency disagrees, however, there can be no doubt that other issues about which FGI gathers information, such as drivers of inflation in the United States, energy prices, government transparency and more, are of interest to a significant audience. Accordingly, FGI is an organization that gathers information of interest to a segment of the population.

C. FGI uses its editorial skills to turn raw materials into distinct works.

As the D.C. Circuit Court has stated, “A substantive press release or editorial comment can be a distinct work based on the underlying material, just as a newspaper article about the same documents would be — and its composition can involve ‘a significant degree of editorial discretion.’”²¹ Furthermore, “nothing in principle prevents a journalist from producing ‘distinct work’ that is based exclusively on documents obtained through FOIA.”²²

FGI is an entity that uses its editorial skills to turn raw materials into distinct works. It routinely issues substantive press releases detailing its activities, posted at functionalgovernment.org. These press releases have included substantive analysis of the information gathered by FGI with a significant degree of editorial discretion. FGI has also prepared detailed reports, posted on its website, and FGI provides substantive editorial comment to other journalists, with many news clips posted on website, as well.

Like a newspaper or other media outlet, FGI uses its editorial skills to turn raw materials into distinct works and intends to do so for other subjects as it gathers additional information. Thus, FGI meets this test.

D. FGI distributes its work to an audience.

For purposes of FOIA, “posting content to a public website can qualify as a means of distributing it — notwithstanding that readers have to affirmatively access the content, rather than have it delivered to their doorsteps or beamed into their homes unbidden.”²³ Moreover, while “[t]here is no doubt that the requirement that a requester distribute its work to ‘an audience’ contemplates that the work is distributed to more than a single person . . . beyond requiring that a person or entity have readers (or listeners or viewers), the statute does not specify what size the audience must be.”²⁴ Additionally, “[t]he fact that [a media entity’s] readership is relatively small ... is irrelevant.”²⁵

Assessing whether a media entity distributes its work to an audience includes consideration of “past record, current operations, and future plans jointly.”²⁶

In addition, the court rejected “the suggestion that a public interest advocacy organization cannot satisfy the statute’s distribution criterion because it is ‘more like a middleman for dissemination to

²¹ *Cause of Action*, 799 F.3d 1122 (quoting *Nat. Sec. Archive v. U.S. Dept. of Defense*, 880 F.2d 1381, 1387 (D.C. Cir. 1989)).

²² *Id.*

²³ *Cause of Action*, 799 F.3d at 1123.

²⁴ *Id.* at 1124 (footnote omitted).

²⁵ *Id.* at 1124 (quoting *Tax Analysts v. Dept. of Justice*, 965 F.2d 1092, 1095 (D.C. Cir. 1992)).

²⁶ *Id.* at 1124.

the media than a representative of the media itself,” concluding “there is no indication that Congress meant to distinguish between those who reach their ultimate audiences directly and those who partner with others to do so, as some recognized journalistic enterprises do.”²⁷

FGI will continue to use its website to distribute original editorial content, including press releases. FGI has email subscribers and intends to establish a greater social media presence to reach its audience directly. In addition, FGI has durable relationships with a broad network of reporters, bloggers, and media publications interested in its content and with whom FGI has partnered to distribute its distinct editorial commentary.

Accordingly, FGI distributes its work to an audience.

E. FGI qualifies as a representative of the news media.

Under the applicable law, a government accountability group qualifies as a media organization for purposes of FOIA when it gathers information of potential interest and uses it to create original content, which can be as simple as issuing a press release or comment to other media organizations, and distributes it, which can be as simple as posting it on a website with an audience greater than one. This is true even if an organization is new and does not have a long track record. Accordingly, under the standard set forth in FOIA and interpreted in *Cause of Action*, FGI clearly qualifies as a representative of the news media.

FGI QUALIFIES FOR A FULL FEE WAIVER.

For all the foregoing reasons, FGI qualifies for a full fee waiver. At minimum, FGI qualifies as a representative of the news media that is exempt from search and production costs. We anticipate that you will promptly grant our fee waiver request and begin to search and disclose the requested records without any unnecessary delays.

Thank you for your prompt attention to this request. If you have any questions, please contact me. Records and any related correspondence should be sent to my attention to the email address below.

Sincerely,

Chris Stanley
Director
Functional Government Initiative
6218 Georgia Avenue NW, Ste 1 - 1235
Washington, DC 20011-5125
chris@functionalgovernment.org

²⁷ *Id.* at 1125 (citations omitted).