Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

October 2016
OTC

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Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
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Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance addresses the process by which the Food and Drug Administration (FDA or Agency) intends to carry out section 586C(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360fff-3(c)), as amended by Public Law 113-195 (also referred to as the Sunscreen Innovation Act (SIA)).[2] Under the SIA, the Agency may convene the Advisory Committee (also referred to in this guidance as the Nonprescription Drugs Advisory Committee or NDAC)[3] to provide recommendations on requests submitted to FDA for a determination of whether a sunscreen active ingredient or combination of sunscreen active ingredients, for use under specified conditions, is generally recognized as safe and effective (GRASE) and should be added to the over-the-counter (OTC) sunscreen drug monograph system. However, section 586C(c) of the FD&C Act provides specific circumstances under which FDA is *not* required to convene or submit requests to the NDAC. The SIA also added section 586D(a)(1) to the FD&C Act (21 U.S.C. 360fff-4(a)(1)), which directs FDA to issue a draft guidance and a final guidance on the process by which FDA will carry out section 586C(c) of the FD&C Act, including with respect to how FDA will address the total number of requests received under section 586A (21 U.S.C. 360fff-1) and pending requests, as defined by the SIA.[4]

The recommendations in this guidance apply to section 586A requests and to pending requests. A 586A request seeks a determination from FDA on whether a nonprescription sunscreen active

[1] This guidance has been prepared by the Office of Regulatory Policy in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

[2] 21 U.S.C. Ch. 9 Sub. 5 Part 1, enacted November 26, 2014.

[3] The SIA defines "Advisory Committee" to mean the Nonprescription Drugs Advisory Committee of the Food and Drug Administration or any successor to such Committee (section 586(1) of the FD&C Act (21 U.S.C. 360fff(1))).

[4] The draft guidance was issued in November 2015 (80 FR 72972, Nov. 23, 2015).

ingredient,[5] or a combination of nonprescription sunscreen active ingredients, is GRASE for use under specified conditions and should be included in the OTC sunscreen drug monograph (section 586A of the FD&C Act). Section 586(6) of the FD&C Act (21 U.S.C. 360fff(6)), as amended by the SIA, defines a "pending request" to mean a request for a nonprescription sunscreen active ingredient submitted under § 330.14 (21 CFR 330.14) for consideration for inclusion in the OTC monograph that was determined to be eligible for review and for which safety and effectiveness data were submitted prior to the enactment of the SIA.[6]

We have published a number of *Federal Register* notices about rulemaking actions for OTC sunscreen monograph products and about actions taken under the SIA. Information on these notices can be found on our "Status of OTC Rulemakings" [7] and "Sunscreen"[8] Web sites.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Advisory Committees and the Nonprescription Drugs Advisory Committee

FDA has established advisory committees "to secure independent professional expertise in accomplishing its mission and maintaining the public trust."[9] FDA's advisory committees provide independent expert advice to the Agency on a range of complex scientific, technical, and policy issues. An advisory committee meeting also provides a forum for a public hearing on important matters. Although advisory committees provide important advice and

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[5] A "sunscreen," as defined in the SIA, means a drug containing one or more sunscreen active ingredients (section 586(9) of the FD&C Act (21 U.S.C. 360fff(9))), and the term "sunscreen active ingredient" means an active ingredient that is intended for application to the skin of humans for purposes of absorbing, reflecting, or scattering ultraviolet radiation (section 586(10) of the FD&C Act (21 U.S.C. 360fff(10))).

[6] These pending requests were submitted as time and extent applications (TEAs) under section 21 CFR 330.14 of FDA's regulations.

[7] The "Status of OTC Rulemakings" Web site is available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/default.htm.

[8] The "Sunscreen" Web site is available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm239463.htm.

[9] See guidance for industry, *Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997* (Advisory Committee Guidance), at 1, available at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm079765.pdf.

recommendations to FDA, the Agency has sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee.[10]

The NDAC was established under the Federal Advisory Committee Act[11] (in addition to other statutory and regulatory provisions), which sets forth requirements for the formation and utilization of advisory committees. Part 14 (21 CFR part 14) describes the procedures and rules that govern the Agency's use of advisory committees (such as the NDAC).

The NDAC reviews and evaluates available data concerning the safety and effectiveness of OTC drug products for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Agency on the requirements for monographs establishing conditions under which these drugs are GRASE and not misbranded.[12] The NDAC consists of approximately 10 voting members selected from among specialists knowledgeable in the fields of internal medicine, family practice, pediatrics, statistics, clinical toxicology, clinical pharmacology, pharmacy, and related specialties.[13] The Agency may call upon individuals to supplement the core membership on an ad hoc basis so that the group considering an issue presented to an advisory committee may also include members who are specialists with expertise in the particular disease or condition for which the drug product under consideration is proposed to be indicated.[14] For example, NDAC committees considering matters related to sunscreens may be supplemented with dermatologists.

FDA recognizes that advisory committee meetings impose significant resource commitments on advisory committee members, sponsors, and other public participants, as well as on the Agency itself, and therefore FDA seeks to limit use of such meetings to *important* matters. In general, FDA has discretion to decide whether to present a matter to an advisory committee— here, to the NDAC—for consideration. In making this decision, FDA generally considers several factors, including the following:

(a) Is the matter at issue of such significant public health importance that it would be highly beneficial to obtain the advice of an advisory committee as part of the Agency's regulatory decision-making process?

(b) Is the matter at issue so controversial that it would be highly beneficial to obtain the advice of an advisory committee as part of the Agency's regulatory decision-making process?

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[10] Id.

[11] Public Law 92-463 (5 U.S.C. Appendix).

[12] See the NDAC Charter, available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/ucm105992.htm.

[13] Id.

[14] Advisory Committee Guidance, supra note 9, at 2.

(c) Is there a special type of expertise that an advisory committee could provide that is needed for the Agency to fully consider a matter?

If one or more of these factors are met, FDA generally refers the matter at issue to an advisory committee. Conversely, FDA generally refrains from referring a matter to an advisory committee if none of the factors are met. By prioritizing matters according to these factors, FDA helps ensure that the finite resources of the advisory committee program are devoted to consideration of the most important matters, including those matters in which the Agency would most benefit from the advice of outside experts.

Specifically for the NDAC, if FDA determines that it would be useful to convene a meeting to discuss sunscreen active ingredients being considered through the SIA process, the Agency would generally make the following preparations, including, but not limited to: (1) identifying additional members, if necessary, for each NDAC meeting who are specialists on the issue(s) to be considered, as well as determining their availability and screening them for conflict-of-interest; (2) preparing FDA briefing information and presentations; (3) publishing notice of the NDAC meeting in the *Federal Register*; and (4) organizing the logistics of setting up and holding the NDAC meeting. Based on the Agency's experience with past NDAC meetings, it may take 4 to 6 months to prepare for an NDAC meeting.

B. Regulation of OTC Sunscreen Products

All sunscreen products are regulated as drugs in the United States under one of two processes:

- The new drug approval process described in 21 CFR part 314
- The OTC drug monograph process (also known as the OTC Drug Review) described in part 330 (21 CFR part 330), as supplemented by the SIA

Products regulated under the new drug approval process may not be marketed without FDA's prior review and approval of a new drug application (NDA) or abbreviated new drug application (ANDA) for each product.[15] Products marketed under the OTC drug monograph process are not individually reviewed and approved prior to marketing. Instead, OTC drug monographs categorize drugs by therapeutic categories, such as sunscreens. For each category, a monograph establishes conditions under which any drug that satisfies those conditions and FDA's general regulations for OTC drugs is considered to be GRASE and not misbranded when used under the conditions prescribed, recommended, or suggested in the drug's labeling.[16]

Active ingredients that were used in U.S.-marketed sunscreens before the OTC Drug Review began are eligible to be included in the OTC sunscreen monograph. An active ingredient or other condition that is ineligible for inclusion in the OTC monograph system is subject to the new drug approval process.

[15] See sections 505(a) and 301(d) of the FD&C Act.

[16] 21 CFR Part 330.

In 2002, before the SIA was enacted, FDA published the "time and extent application" (TEA) regulation in 21 CFR 330.14. The TEA regulation (§ 330.14(c)) has provided a process through which any person may request that FDA amend an existing OTC drug monograph to include an active ingredient or other OTC drug condition, including one not previously marketed in the United States before the OTC Drug Review began.

For OTC sunscreens, the SIA process supplements FDA's TEA regulation (§ 330.14). The SIA amended the FD&C Act in part by providing new procedures for establishing that nonprescription sunscreen active ingredients or combinations of nonprescription sunscreen active ingredients are GRASE and not misbranded when used under the conditions specified in a final sunscreen order (GRASE determination).[17] Active ingredients that are determined to be GRASE under specified conditions of use in a final sunscreen order may be used in U.S.-marketed sunscreens without first obtaining an approved NDA or ANDA. Because the monograph and SIA processes are public, anyone, not just the sponsor who originated the request, may submit data during public comment periods.

As with the TEA process, the SIA process calls for an initial eligibility determination, followed by submissions of safety and efficacy data, and a GRASE determination phase. However, the SIA process also requires FDA to make a filing determination[18] and to make proposed and final GRASE determinations in the form of orders rather than the rulemaking required by the TEA regulation. The SIA process also establishes strict timelines for the necessary administrative actions. At certain stages in the SIA process, FDA has the discretion to convene the NDAC for the purpose of reviewing and providing recommendations on a 586A request or on a pending request.

C. Related Guidance

In addition to this guidance, the SIA directs FDA to issue draft and final guidance documents on three other topics.[19] These topics include:

- The format and content of information submitted by a sponsor in support of a 586A request or a pending request;

- The data required to meet the safety and efficacy standard for determining whether a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and not misbranded; and

[17] Section 586C of the FD&C Act (21 U.S.C. 360fff-3).

[18] The filing determination requires FDA to determine whether the safety and efficacy data submitted to support a GRASE determination are appropriately formatted and sufficiently complete to support a substantive GRASE review (section 586B(b)(2) of the FD&C Act (21 U.S.C. 360fff-2(b)(2))).

[19] Section 586D(a)(1)(A) of the FD&C Act (21 U.S.C. 360fff-4(a)(1)(A)).

- The process for withdrawing a 586A request or a pending request.

In November 2015, FDA issued draft guidance on all four topics. As they become available, draft or final guidances are posted on the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.[20]

III. SECTION 586C(c) OF THE FD&C ACT

Section 586D(a)(1)(A)(iv) of the FD&C Act (21 U.S.C. 360fff-4(a)(1)(A)(iv)) requires FDA to issue guidance on the process it will use to carry out section 586C(c) of the FD&C Act, including with respect to how FDA will address the total number of requests received under section 586A and pending requests.[21] Section 586C(c) of the FD&C Act states that:

- FDA is not required to convene the NDAC "more than once with respect to any request under section 586A or any pending request."

- FDA is not required to convene the NDAC "more than twice in any calendar year with respect to the review under this section."

- FDA is not required to "submit more than a total of 3 requests under section 586A or pending requests to the Advisory Committee per meeting."[22]

Below, we describe how we intend to carry out section 586C(c), including how we intend to handle the total number of 586A requests and pending requests.

As an initial matter, a sponsor can request that FDA convene the NDAC to consider certain issues related to the sponsor's 586A request or pending request. (An NDAC meeting is not meant to take the place of the public feedback meetings with CDER, which are provided for elsewhere in the SIA.[23]) To provide adequate time for the parties to prepare for an NDAC meeting, we recommend that (1) sponsors of 586A requests that are interested in seeking an NDAC meeting submit their request for such a meeting at the time they submit their initial data package, or no later than at the time of the filing determination; and (2) sponsors of pending requests that are interested in seeking an NDAC meeting submit their request for such a meeting at the time they submit their supplemental data package.

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[20] When available, FDA will post each final guidance on the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[21] Section 586D of the FD&C Act (21 U.S.C. 360fff-4).

[22] Section 586C(c) of the FD&C Act.

[23] See, e.g., sections 586B(b)(3)(A) and 586C(a)(4) and (b)(7) of the FD&C Act (21 U.S.C. 360fff-2(b)(3)(A) and 21 U.S.C. 360fff-3(a)(4) and (b)(7)).

The request for an NDAC meeting should be sent as a letter (either by hard copy or electronically) to the Division of Nonprescription Drug Products (DNDP). If there is an applicable docket,[24] a duplicate letter should be sent (either by hard copy or electronically) to the Division of Dockets Management as well. Both addresses are as follows:

> Food and Drug Administration
> Division of Nonprescription Drug Products
> Bldg. 22, Mail Stop 5411
> 10903 New Hampshire Avenue
> Silver Spring, MD 20993
> Electronic letters should be sent to the following e-mail address:
> OTCDrugs@fda.hhs.gov
>
> Food and Drug Administration
> Division of Dockets Management (HFA-305)
> 5630 Fishers Lane, Rm. 1061
> Rockville, MD 20852
> Electronic letters should be submitted at http://www.regulations.gov in the applicable docket.

We recommend the sponsor submit the following information as part of a request for an NDAC meeting:

1. The subject line should be prominently labeled: "SIA (586A Request/Pending Request) - Request that FDA Convene the Nonprescription Drugs Advisory Committee."

2. The body of the letter should contain the following:

   - A statement that the sponsor requests FDA to convene the NDAC for review and recommendations regarding a 586A request or a pending request for a sunscreen active ingredient or combination of sunscreen active ingredients under specified conditions of use.

   - Information about the specific sunscreen active ingredient or combination of sunscreen active ingredients and specified conditions of use to be the subject of the requested NDAC meeting.

   - The name of the specific sponsor that will present information to the NDAC.

   - A statement of the specific matter proposed for discussion at the NDAC meeting.

   - A statement explaining why the specific matter warrants NDAC discussion and why it should be considered at the particular time of the request.

[24] If no docket has been opened for the matter, the request should be sent only to the DNDP.

- As applicable, the statement should refer to the factors discussed above in Section II.A in support of the request for an NDAC meeting.

3. The name, title, address, telephone number, and e-mail address of the sponsor's contact person should be included.

Upon receipt of the NDAC request,[25] DNDP intends to review the letter. FDA intends to consider an NDAC request to have been made when the Agency acknowledges receipt of the request letter. DNDP intends to provide an acknowledgment letter to the sponsor within 30 days of receipt. Acknowledgment of the receipt of the request does not constitute an agreement by FDA to convene the NDAC. If FDA decides that the NDAC will be convened, FDA will notify the sponsor.

Under the SIA, FDA may decide whether to convene an NDAC for any particular 586A request or pending request regardless of whether the sponsor has made an NDAC request. FDA intends to address and prioritize the total number of 586A requests and pending requests received by using the factors described in Section II.A above to determine whether and when to refer such a request to the NDAC. For example, FDA would be more likely to convene a meeting for matters that are dissimilar to those discussed at a previous NDAC and for which a clear path forward had not already been determined. In addition, FDA may convene an NDAC on its own initiative, using similar criteria as those factors used to determine whether to present sponsor requests to an NDAC.

As explained above, referring a matter to the NDAC involves a substantial expenditure of the Agency's limited resources and time. Accordingly, depending on the total number of 586A requests and pending requests to be considered by the NDAC, FDA intends to limit the number of NDAC meetings per year and the number of requests to be considered per meeting as discussed in section 586C(c) of the FD&C Act.

IV. PREPARATION AND PUBLIC AVAILABILITY OF INFORMATION GIVEN TO ADVISORY COMMITTEE MEMBERS

For each advisory committee meeting, the sponsor should provide briefing materials to be considered by the members of the NDAC. For most meetings, these materials should consist of the sponsor's briefing document which addresses the issues to be considered by the NDAC. The briefing document should include all information relevant to the matters to be discussed at the NDAC meeting, presented in a concise summary. Information on briefing material preparation, timelines, and public availability of briefing material is included in the guidance for industry

[25] The official date of receipt of the letter may be assigned by FDA and may not necessarily be the date of mailing or of delivery by a delivery service.

Advisory Committee Meetings —Preparation and Public Availability of Information Given to Advisory Committee Members.[26]

[26] Available at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-gen/documents/document/ucm125650.pdf.