



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2005-N-0453, FDA-2003-N-0196, and FDA-2006-O-0314]

Sunscreen Feedback Letters; Notice of Availability Under the Sunscreen Innovation Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of letters containing FDA's initial determinations and feedback on safety and effectiveness data submitted to demonstrate that certain active ingredients are generally recognized as safe and effective (GRASE) and not misbranded for use in over-the-counter (OTC) sunscreen drug products (sunscreen feedback letters). We are taking this action under the Sunscreen Innovation Act (SIA).

DATES: Submit either electronic or written comments by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Sponsors may submit written requests for a meeting with FDA to discuss these proposed sunscreen orders by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should clearly identify the specific active ingredient(s) and docket number(s) to which the comments apply.

FOR FURTHER INFORMATION CONTACT: Kristen Hardin, Division of Nonprescription Drug Products, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5491, Silver Spring, MD 20993-0002, 240-402-4246.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of six sunscreen feedback letters on its Web site that contain the Agency's tentative determinations and feedback on safety and effectiveness data submitted to demonstrate that certain active ingredients are GRASE and not misbranded for use in OTC sunscreen drug products. We are taking this action under the SIA (Public Law 113-195), enacted November 26, 2014. Before the SIA was enacted, these sunscreen feedback letters were issued to persons seeking OTC monograph status for nonprescription sunscreen active ingredients using the Time and Extent Application (TEA) process under FDA regulations in 21 CFR 330.14, and were also previously made available to the public in the docket.

The SIA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to, among other things, provide an alternative process for FDA to review the safety and effectiveness of nonprescription sunscreen active ingredients. The SIA establishes new procedures for establishing the conditions under which sunscreens containing active ingredients that have been reviewed through the SIA process and found in a final sunscreen order to be GRASE and not misbranded may be marketed in the United States.

Section 586C(b)(3) of the FD&C Act, as added by the SIA, provides that sunscreen feedback letters issued before the SIA was enacted are deemed to be proposed sunscreen orders. Proposed sunscreen orders contain FDA's tentative determination that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients: (A)

is GRASE and not misbranded if marketed in accordance with such order; (B) is not GRASE and is misbranded; or (C) is not GRASE and is misbranded because the data are insufficient to classify the active ingredient or combination of ingredients as GRASE and not misbranded, and additional data are necessary to allow FDA to determine otherwise. All of the proposed sunscreen orders addressed in this notice have been tentatively classified under category (C), as described in the previous sentence. Accordingly, additional data will be needed to support a determination that any or all of the active ingredients they address are GRASE and not misbranded.

II. Sunscreen Feedback Letters Deemed to Be SIA Proposed Orders

The six feedback letters that are deemed to be proposed orders under the SIA are identified in Table 1. They can be viewed electronically on FDA’s Web site at <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm239463.htm>, under the heading “FDA Regulatory Action on Sunscreen.” Related documents, including safety and efficacy data submissions, can be accessed in the corresponding dockets, identified in Table 1, at <http://www.regulations.gov>. The letters and associated information may also be viewed by visiting FDA’s Division of Dockets Management (see ADDRESSES).

Table 1--OTC Sunscreen Feedback Letters Deemed to be SIA Proposed Orders

Active Ingredient	Sponsor	Date Issued	Docket No. ¹
Bemotrizinol	Ciba Specialty Chemicals Corp.	11/13/2014	FDA-2005-N-0453
Bisotrizole	Ciba Specialty Chemicals Corp.	9/3/2014	FDA-2005-N-0453
Drometrizole Trisiloxane	L’Oreal USA Products, Inc.	8/29/2014	FDA-2003-N-0196
Octyl Triazone	BASF AG	6/23/2014	FDA-2003-N-0196
Amiloxate	Symrise, Inc. Ego Pharmaceuticals Pty. Ltd.	2/25/2014	FDA-2003-N-0196
Diethylhexyl Butamido Triazone	3V Inc.	2/21/2014	FDA-2006-O-0314

¹ Each letter was previously posted in the docket shown in Table 1 on the date that it was issued.

Sponsors may submit a written request for a meeting with FDA to discuss any of these proposed sunscreen orders (see DATES). Submit meeting requests electronically to www.regulations.gov or in writing to the Division of Dockets Management (see ADDRESSES), identified with the active ingredient name(s), the corresponding docket number(s) shown in Table 1, and the heading “Sponsor Meeting Request.” To facilitate your request, please also send a copy to Kristen Hardin (see FOR FURTHER INFORMATION CONTACT).

III. Comments

Interested persons may submit either electronic comments about the proposed orders discussed in this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the appropriate docket number(s) and active ingredient name(s) shown in Table 1 for the proposed order(s) that the comments address. Comments on this notice may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the appropriate docket(s) at <http://www.regulations.gov>.

Dated: December 31, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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