

Board of Governors of the Federal Reserve System, January 2, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

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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 February 23, 2015. Sponsors may submit written requests for a meeting with FDA to discuss these proposed sunscreen orders by February 6, 2015.

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 (Pub. L. 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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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2550-14; DHS Docket No. USCIS-2007-0028]

RIN 1615-ZB36

Extension of the Designation of El Salvador for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Through this Notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) is extending the designation of El Salvador for Temporary Protected Status (TPS) for 18 months from March 10, 2015, through September 9, 2016.

The extension allows currently eligible TPS beneficiaries to retain TPS through September 9, 2016, so long as they otherwise continue to meet the eligibility requirements for TPS. The Secretary has determined that an extension is warranted because the conditions in El Salvador that prompted the TPS designation continue to be met. There continues to be a substantial, but temporary, disruption of living conditions in El Salvador resulting from a series of earthquakes in 2001, and El Salvador remains unable, temporarily, to handle adequately the return of its nationals.

Through this Notice, DHS also sets forth procedures necessary for nationals of El Salvador (or aliens having no nationality who last habitually resided in El Salvador) to re-register for TPS and to apply for renewal of their Employment Authorization Documents (EADs) with U.S. Citizenship and Immigration Services (USCIS). Re-registration is limited to persons who have previously registered for TPS under the designation of El Salvador and whose applications have been granted. Certain nationals of El Salvador (or aliens having no nationality who last habitually resided in El Salvador) who have not previously applied for TPS may be eligible to apply under the late initial registration provisions, if they meet: (1) At least one of the late initial filing criteria; and, (2) all TPS eligibility criteria (including continuous residence in the United States since February 13, 2001, and continuous physical presence in the United States since March 9, 2001).

For individuals who have already been granted TPS under the El Salvador designation, the 60-day re-registration period runs from January 7, 2015 through March 9, 2015. USCIS will issue new EADs with a September 9, 2016 expiration date to eligible El Salvador TPS beneficiaries who timely re-register and apply for EADs under this extension. Given the timeframes involved with processing TPS re-registration applications, DHS recognizes that not all re-registrants will receive new EADs before their current EADs expire on March 9, 2015. Accordingly, through this Notice, DHS automatically extends the validity of EADs issued under the TPS designation of El Salvador for 6 months, through September 9, 2015, and explains how TPS beneficiaries and their employers may determine which EADs are automatically extended and their impact on Employment Eligibility Verification (Form I-9) and the E-Verify processes.

DATES: The 18-month extension of the TPS designation of El Salvador is effective March 10, 2015, and will remain in effect through September 9, 2016. The 60-day re-registration period runs from January 7, 2015 through March 9, 2015. (Note: It is important for re-registrants to timely re-register during this 60-day re-registration period and not to wait until their EADs expire.)

FOR FURTHER INFORMATION CONTACT:

- For further information on TPS, including guidance on the application process and additional information on eligibility, please visit the USCIS TPS Web page at <http://www.uscis.gov/tps>. You can find specific information about this extension of El Salvador for TPS by selecting "TPS Designated Country: El Salvador" from the menu on the left of the TPS Web page.

- You can also contact the TPS Operations Program Manager at the Family and Status Branch, Service Center Operations Directorate, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529-2060; or by phone at (202) 272-1533 (this is not a toll-free number). **Note:** The phone number provided here is solely for questions regarding this TPS Notice. It is not for individual case status inquiries.

- Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at 800-375-5283 (TTY 800-767-1833). Service is available in English and Spanish.

- Further information will also be available at local USCIS offices upon publication of this Notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA—Board of Immigration Appeals
 DHS—Department of Homeland Security
 DOS—Department of State
 EAD—Employment Authorization Document
 FNC—Final Nonconfirmation
 Government—U.S. Government
 JJ—Immigration Judge
 INA—Immigration and Nationality Act
 OSC—U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices
 SAVE—USCIS Systematic Alien Verification for Entitlements Program
 Secretary—Secretary of Homeland Security
 TNC—Tentative Nonconfirmation
 TPS—Temporary Protected Status
 TTY—Text Telephone
 USCIS—U.S. Citizenship and Immigration Services