DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

May 24, 2016

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This letter is being provided pursuant to a requirement under the Sunscreen Innovation Act of 2014 (SIA) to provide your Committee with a report regarding certain non-sunscreen time and extent applications (TEAs). Specifically, among other things, the SIA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require the Food and Drug Administration (FDA) to provide a report to your Committee on the review of TEAs subject to section 586F(a)(1) of the FD&C Act,[1] including the timelines for the review and FDA's generally recognized as safe and effective (GRASE) determination for each of these TEAs, with the report due by May 26, 2016. See Sec. 586F(a)(4) (Letter Regarding Pending Applications) of the FD&C Act.

FDA Review Frameworks

Six non-sunscreen TEAs were pending with FDA prior to the date of enactment of the SIA (see attached table for more information). Sponsors for three of the TEAs requested and selected a review framework in accordance with section 586F(a) of the FD&C Act. Each selected framework is summarized in the attached table.

FDA will review submissions for TEAs for which the sponsor selected a review framework according to the timelines applicable to the option chosen by the sponsor. TEAs for which the sponsor did not request a framework for review will be reviewed in accordance with the timelines that are to be established in the final rule that the SIA requires FDA to issue under section 586F(b) of the FD&C Act.[2] This letter is also being sent to Senator Patty Murray and Representatives Fred Upton and Frank Pallone.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Attachment

[1] Section 586F(a)(1) provides that if a TEA for a drug other than a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients was submitted to FDA before the SIA was enacted, and the drug was found to be eligible to be considered for inclusion in the OTC drug monograph system under FDA regulations, the sponsor of the TEA may request a framework for review of the application under section 586F(a)(2) of the FD&C Act.

[2] See section 586F(a)(1)(C) of the FD&C Act. With regard to the final rule required by section 586F(b) of the FD&C Act, there are two relevant statutory deadlines. The proposed rule was due by May 26, 2016 (FDA published this proposed rule in the *Federal Register* on April 4, 2016 (81 FR 19069)), and the final rule is due by February 26, 2017.

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Silver Spring, MD 20993

May 24, 2016

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Senator Murray:

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May 24, 2016

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20510

Dear Mr. Chairman:

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Silver Spring, MD 20993

May 24, 2016

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Representative Pallone:

This letter is being provided pursuant to a requirement under the Sunscreen Innovation Act of 2014 (SIA) to provide your Committee with a report regarding certain non-sunscreen time and extent applications (TEAs). Specifically, among other things, the SIA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require the Food and Drug Administration (FDA) to provide a report to your Committee on the review of TEAs subject to section 586F(a)(1) of the FD&C Act,[1] including the timelines for the review and FDA's generally recognized as safe and effective (GRASE) determination for each of these TEAs, with the report due by May 26, 2016. See Sec. 586F(a)(4) (Letter Regarding Pending Applications) of the FD&C Act.

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Attachment 1: Table of Pending Non-Sunscreen TEAs

Active Ingredient	Type of Drug	Sponsor Request for Review Framework?	Framework for Review	Status
Sodium Picosulfate FDA-2006-O-0057	Laxative	**Yes**	**Option 1: Order process with no filing determination** (see FD&C Act section 586F(a)(1)(B)(i)) FDA issues a proposed order within 912 days (2.5 years) after receiving the review option selection. Final order publishes 547 days (1.5 years) after the proposed order comment period closes.	Review option selection received by FDA on January 22, 2016. Safety and effectiveness data currently under review. Proposed order due by July 22, 2018.
Piroctone Olamine FDA-2004-N-0037	Anti-dandruff	**Yes**	**Option 3: Order process with a filing determination** (see FD&C Act section 586F(a)(1)(B)(iii)) FDA issues a filing determination within 90 days after receiving the review option selection. FDA issues a proposed order within 730 days (2 years) after the date of filing. FDA issues a final order within 547 days (1.5 years) after the proposed order comment period closes.	Review option selection received by FDA on December 18, 2015. On March 16, 2016, FDA issued a refuse-to-file determination for the safety and effectiveness data submission for piroctone olamine, meeting the 90-day timeline. FDA determined that the submission was not sufficiently complete for substantive review. The sponsor requested a meeting with FDA regarding the refuse-to-file determination and FDA offered a meeting date to the sponsor within 30 days of the request, as set forth in the review framework. The sponsor subsequently withdrew the meeting request.

Attachment 1: Table of Pending Non-Sunscreen TEAs

Active Ingredient	Type of Drug	Sponsor Request for Review Framework?	Framework for Review	Status
Sodium Shale Oil Sulfonate FDA-2009-N-0146	Anti-dandruff	**Yes**	**Option 3: Order process with a filing determination** (see FD&C Act section 586F(a)(1)(B)(iii)) FDA issues a filing determination within 90 days after receiving the review option selection. FDA issues a proposed order within 730 days (2 years) after the date of filing. FDA issues a final order within 547 days (1.5 years) after the proposed order comment period closes.	Review option selection received by FDA on January 21, 2016. On April 20, 2016, FDA issued a refuse-to-file determination for the safety and effectiveness data submission for sodium shale oil sulfonate, meeting the 90-day timeline. FDA determined that the submission was not sufficiently complete for substantive review. The sponsor has 30 days to request a meeting with FDA regarding the refuse-to-file determination. The sponsor may also submit additional data in response to the refuse-to-file determination.
Triclosan FDA-1981-N-0015	Anti-gingivitis	**No**	As provided in SIA-required regulation, when finalized.	As provided in section 586F(a)(1)(C) of the FD&C Act, the submission will be reviewed under timelines established by regulation under 586F(b), once finalized.
Triclosan FDA-2005-N-0454	Acne treatment	**No**	As provided in SIA-required regulation, when finalized.	As provided in section 586F(a)(1)(C) of the FD&C Act, the submission will be reviewed under timelines established by regulation under 586F(b), once finalized.
Climbazole FDA-2005-N-0021	Anti-dandruff	**No**	As provided in SIA-required regulation, when finalized.	As provided in section 586F(a)(1)(C) of the FD&C Act, the submission will be reviewed under timelines established by regulation under 586F(b), once finalized.