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, 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. 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

---

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.
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:

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 Lamar Alexander and Representatives Fred Upton and Frank Pallone.

Sincerely,

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

---

\(^1\) 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 19089)), and the final rule is due by February 26, 2017.
May 24, 2016

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
United States House of Representatives
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, 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. This letter is also being sent to Senators Lamar Alexander, Patty Murray and Representative Frank Pallone.

Sincerely,

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

---

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 19089)), and the final rule is due by February 26, 2017.
The Honorable Frank Pallone  
Ranking Member  
Committee on Energy and Commerce  
United States House of Representatives  
Washington, DC 20515

May 24, 2016

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.

**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 Representative Fred Upton and Senators Lamar Alexander and Patty Murray.

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.
<table>
<thead>
<tr>
<th>Status</th>
<th>Framework for Review</th>
<th>Sponsor Request</th>
<th>Type of Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>For Review</td>
<td></td>
<td>Active ingredient</td>
</tr>
<tr>
<td>Yes</td>
<td>For Review</td>
<td></td>
<td>Sodium Phosphurate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Laxative</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>FDAs-2006-O-00057</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>FDAs-2004-N-0037</td>
</tr>
</tbody>
</table>

**Option 1: Order Process with no Final Determination**
- FDA issues a final order within 90 days after the date of filing.
- FDA issues a final order within 365 days (1.5 years) after the date of filing.
- (see FDAC Act Section 506(f)(1)(B)(ii))

**Option 2: Order Process with a Final Determination**
- FDA issues a final order within 547 days (1.5 years) after the date of filing.
- FDA issues a final order within 730 days (2 years) after the date of filing.
- (see FDAC Act Section 506(f)(a)(B)(ii))

**Procedure Overview**
- The sponsor received a meeting with the Sponsor Request Framework. The sponsor recommended a meeting with the sponsor.
- Days of the request are set forth in the meeting date to the sponsor within 30 days of the meeting.
- FDA notified the sponsor of the review of the proposed order.
- On March 16, 2016, FDA issued a review option selection received by the sponsor.
- On December 18, 2015, FDA issued a review option selection received by the sponsor.
- On February 22, 2016, FDA issued a review option selection received by the sponsor.
- On July 22, 2018, FDA issued a review option selection received by the sponsor.
- On January 22, 2016, FDA issued a review option selection received by the sponsor.
<table>
<thead>
<tr>
<th>Status</th>
<th>Framework for Review</th>
<th>Sponsor Request</th>
<th>Type of Drug</th>
<th>Active Ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review Option Section received by FDA on January 2, 2016</td>
<td>Yes</td>
<td>Yes</td>
<td>\text{Sodium Sulfate}</td>
<td>\text{Sodium Sulfate}</td>
</tr>
<tr>
<td>The sponsor has 30 days to request a complete re-submission review.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The submission was not substantially amended before the 90-day limit. FDA determined the sponsor failure to submit the re-submission for the delayed and effectiveness data submission for the 2.5 years after the date of filing.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA issues a final order within 347 days (1.5 years) after the date of filing.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA issues a final order within 730 days (2 years) after the date of filing.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA issues a final order within 90 days after the date of filing.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Option 3: Order Process with a Final Determination**

---

**Attachment I: Table of Pending Non-Sustainable TEAS**