Appendix A: Status of Pending SIA Requests

Ingredient [Docket No.]	Date of Time and Extent Application	Eligibility Determination Date	Date(s) of Industry Data Submission	Feedback Letter Issued (Deemed by SIA's enactment to be Proposed Sunscreen Order)	Statutory Deadline for Proposed Sunscreen Order or Notice Thereof (in case of prior Feedback Letter)	Date Proposed Sunscreen Order or Notice Issued	Date of Industry Submission of Missing Data	Date Final Sunscreen Order Issued
Bemotrizinol [FDA-2005-N-0453]	4/11/05	12/5/2005	2/28/2006 11/29/2006	11/13/2014	1/10/2015	1/7/2015	Pending[1]	Pending data submission
Bisoctrizole [FDA-2005-N-0453]	4/11/05	12/5/05	2/27/06	9/3/2014	1/10/2015	1/7/2015	Pending[1]	Pending data submission
Drometrizole Trisiloxane [FDA-2003-N-0196]	1/16/2009	6/2/10	1/16/09 7/14/10	8/29/2014	1/10/2015	1/7/2015	Pending[2]	Pending data submission
Octyl Triazone [2003N-0233]	8/21/02	7/11/03	10/3/03 1/9/04 7/2/04 12/21/06	6/23/2014	1/10/2015	1/7/2015	Pending[1]	Pending data submission
Amiloxate [2003N-0233 SUP3 and RPT1]	8/14/02	7/11/03	10/1/03 8/15/03	2/25/2014	1/10/2015	1/7/2015	Pending; No contact from sponsor since 2003	Pending data submission

[1] Meetings held with BASF, the sponsor of bemotrizinol, bisoctrizole, and octyl triazone on March 19, 2015, and March 20, 2015. Detailed written responses to all sponsor questions and minutes of these meetings were provided. FDA provided additional written feedback on October 8, 2015. Then-FDA Acting Commissioner Dr. Ostroff and then-Deputy Commissioner Dr. Califf held a call with BASF senior management on June 2, 2015. The sponsor has submitted no data or protocols for review.

[2] Meeting held with L'Oreal, the sponsor of drometrizole, trisiloxane, and ecamsule on May 11, 2015. Detailed written responses to all sponsor questions and minutes of this meeting were provided. FDA provided additional written feedback on August 31, 2015, December 14, 2015, and March 25, 2016. Then-FDA Acting Commissioner Dr. Ostroff and then-Deputy Commissioner Dr. Califf held a call with L'Oreal senior management on May 19, 2015. The sponsor has submitted no data or protocols for review.

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Diethylhexyl Butamido Triazone [FDA-2006-0-0314]	9/16/05	7/26/06	10/24/06 7/6/07 5/6/10	2/21/2014	1/10/2015	1/7/2015	Pending; No contact from sponsor since 2010	Pending data submission
Ecamsule[3] 9FDA-2008-N-0474]	9/19/07	9/12/08	11/14/08	Not applicable	2/24/2015	2/24/2015	Pending[2]	Pending data submission
Enzacamene[4] [2003N-0233]	8/21/02	7/11/03	10/9/03	Not applicable	2/24/2015	2/24/2015	Pending; No contact from sponsor since 2003	Pending data submission

[3] Ecamsule is already available in four different sunscreen products in the United States, marketed under NDAs 021502, 021501, 021471, and 022009. Currently there are no exclusivities remaining or unexpired patents listed for these applications in FDA's Orange Book, which means that patents and exclusivities would not impact FDA's ability to approve generic versions, thereby potentially increasing availability in the United States if generic approval is sought.

[4] In 2013 (SCCS/151/13), the Scientific Committee on Consumer Safety (SCCS) opined that the use of enzacamene as a UV-filter in cosmetic products in a concentration up to 2.0% is not safe. Their conclusion was based on endocrine disruptor properties, which were also noted in FDA's proposed order. [Note: The European Commission relies on the SCCS for scientific advice on health and safety risks of consumer products, including cosmetics.] In 2011, the French regulatory authorities adopted a decision to prohibit manufacture, import, export, wholesale distribution or marketing of enzacamene-containing products in France. See: SCCS (Scientific Committee on Consumer Safety), Opinion on 3-Benzylidene camphor. Colipa No S61, 18 June 2013.