EXISTING ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Baseline Information Form	8,000	4,000	1	0.2	800
Implementation Study Site Visits	150	75	1	1	75
JSA Staff Survey	440	220	1	0.33	73

Total Previously Approved Annual Burden: 948.

PROPOSED NEW ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
6 Month Follow-Up Survey	6,400	3,200	1	0.333	1,066
Participant Contact Update Form	1,200	600	1	0.083	50
Tracking Surveys	2,800	1,400	5	0.167	1,169

Estimated Total NEW Annual Burden Hours: 2285.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

ACF Reports Clearance Officer.

[FR Doc. 2015–29749 Filed 11–20–15; 8:45 am]

BILLING CODE 4184–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4012]

Sunscreen Innovation Act; Withdrawal of a 586A Request or Pending Request; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request.'' This draft guidance provides recommendations for the process for withdrawing a 586A request submitted under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Sunscreen Innovation Act (SIA), and withdrawing a pending request, as defined by the SIA. The recommendations in this guidance apply to 586A requests and pending requests that seek a determination from FDA of whether a nonprescription sunscreen active ingredient, or a combination of nonprescription sunscreen active ingredients, is generally recognized as safe and effective (GRASE) for use under specified conditions and should be included in the over-the-counter (OTC) sunscreen drug monograph. We are issuing this draft guidance under the SIA, which directs FDA to issue guidance on various topics, including guidance on the process by which a request under section 586A or a pending request is withdrawn.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 22, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–4012 for ''Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kristen Hardin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5443, Silver Spring, MD 20993, 240–402–4246.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request.'' This draft guidance provides background information on the sunscreen OTC monograph process and the new procedures under the SIA (Pub. L. 113–195, enacted November 26, 2014), for reviewing 586A requests (requests made under section 586A of the FD&C Act (21 U.S.C. 360fff–1) and pending requests for nonprescription sunscreen active ingredients (the SIA process). This draft guidance provides recommendations for the general withdrawal process for 586A requests and pending requests. At certain stages of the SIA process, a sponsor who submitted the 586A request or pending request might seek to have it withdrawn, or a request may be withdrawn due to the sponsor's failure to act on the request and failure to respond to communications from FDA. This draft guidance addresses the expected effect of a withdrawal on key phases of the SIA process, including withdrawals made prior to or after the initial eligibility determination, the submission of safety and efficacy data, the filing determination, or the GRASE determination. This draft guidance also discusses the submission of a new 586A request for the same sunscreen ingredient for which a 586A or pending request had been previously submitted and withdrawn.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the withdrawal of 586A requests and pending requests under the SIA. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This draft guidance contains collections of information that are exempt from the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA). Section 586D(a)(1)(C) of the FD&C Act (21 U.S.C 360fff–4(a)(1)(C)) states that the PRA shall not apply to collections of information made for purposes of guidance under section 586D(a).

Dated: November 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29634 Filed 11–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.