number of hospitals that ultimately need to appeal their MGCRB decisions to the CMS Administrator. Form Number: CMS–R–138 (OMB control number: 0938–0573); Frequency: Occasionally; Affected Public: Businesses or other for-profits and Not-for-profit institutions; Number of Respondents: 300; Total Annual Responses: 300; Total Annual Hours: 300. (For policy questions regarding this collection contact Noel Manlove at 410–786–5161.)

2. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Notification of FIs and CMS of co-located Medicare providers; Use: Many long-term care hospitals (LTCHs) are co-located with other Medicare providers (acute care hospitals, IRFs, SNFs, psychiatric facilities), which leads to potential gaming of the Medicare system based on patient shifting. In regulations at 42 CFR 412.32(e)(3) and (b)(6) and 412.532(i), CMS is requiring LTCHs to notify Medicare Administrative Contractors (MACs) and CMS of co-located providers in order to establish policies to limit payment abuse that will be based on FIs tracking patient movement among these co-located providers. Form Number: CMS–10088 (OMB control number: 0938–0897); Frequency: Annually; Affected Public: Businesses or other for-profits and Not-for-profit institutions; Number of Respondents: 25; Total Annual Responses: 25; Total Annual Hours: 6. (For policy questions regarding this collection contact Emily Lipkin at 410–786–3633.)

Dated: October 4, 2016.
William N. Parham, III.
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process.” This guidance explains the process by which FDA intends to carry out the section of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Sunscreen Innovation Act (SIA), which governs the convening of advisory committees to provide recommendations on requests submitted under the SIA regarding nonprescription sunscreen active ingredients and the number of requests to be considered per meeting. The recommendations in this guidance apply to 586A requests submitted under the FD&C Act and to pending requests as defined by the SIA that seek a determination from FDA on 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. The SIA describes specific circumstances under which FDA is not required to convene or submit requests to the Nonprescription Drugs Advisory Committee (NDAC). We are issuing this guidance pursuant to the SIA, which directs FDA to issue guidance on four topics, including the topic discussed in this guidance. This guidance finalizes the draft guidance on the same topic issued on November 23, 2015.

DATES: Submit either electronic or written comments on Agency guidelines at any time.

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–3990 for “Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process.” 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
SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request; Guidance for Industry: Availability”.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

STATEMENT OF PURPOSE AND BACKGROUND: FDA is announcing the availability of guidance for industry entitled “Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request; Guidance for Industry: Availability,” which 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 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. This guidance finalizes the draft guidance issued on November 23, 2015.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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.