(GSA Form 1142, Release of Claims), in all correspondence.

Jeffrey A. Koses,

Director, Office of Acquisition Policy, Office of Government-wide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–1880]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by April 27, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Certification as a Supplier of Portable X-Ray and Portable X-Ray Survey Report Form and Supporting Regulations; *Use:* CMS–1880 is initially completed by suppliers of portable X-ray services, expressing an interest in and requesting participation in the Medicare program. This form initiates the process of obtaining a decision as to whether the conditions of coverage are met as a portable X-ray supplier. It also promotes data reduction or introduction to, and retrieval from, the Certification and Survey Provider Enhanced Reporting (CASPER) by the CMS Regional Offices (ROs). *Form Numbers:* CMS–1880 (OMB control number: 0938–0027); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 86; *Total Annual Responses:* 86; *Total Annual Hours:* 22. (For policy questions regarding this collection contact Peter Ajounoma at 410–786–3580.)

Dated: March 23, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–06221 Filed 3–27–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0878]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by April 27, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0330. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Notification for a New Dietary Ingredient—21 CFR 190.6

OMB Control Number 0910–0330—Extension

This information collection supports Agency regulations and accompanying guidance. Specifically, section 413(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient, the manufacturer or distributor of the dietary supplement or of the new dietary ingredient is to submit to FDA (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. FDA's implementing regulation, § 190.6 (21 CFR 190.6), requires this information to be submitted to the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS) in the form of a notification. Under § 190.6(b), the notification must include the following: (1) the name and complete address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplement(s) that contain the new dietary ingredient, including the level of the new dietary ingredient in the dietary supplement and the dietary supplement's conditions of use, (4) the history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of the dietary supplement, and (5) the signature of a responsible person designated by the manufacturer or distributor.

These premarket notification requirements are designed to enable us to monitor the introduction into the marketplace of new dietary ingredients and dietary supplements that contain new dietary ingredients in order to protect consumers from ingredients and products whose safety is unknown. FDA uses the information collected in new dietary ingredient notifications to evaluate the safety of new dietary ingredients in dietary supplements and to support regulatory action against ingredients and products that are potentially unsafe.

FDA has developed an electronic portal that respondents may use to electronically submit their notifications to ONLDS via FDA Unified Registration and Listing Systems. Firms that prefer to submit a paper notification in a format of their own choosing still have the option to do so; however, Form FDA 3880 prompts a submitter to input the elements of a new dietary ingredient notification (NDIN) in a standard format and helps the respondent organize its NDIN to focus on the information needed for FDA's safety review. Safety information may be submitted via a supplemental form entitled ''New Dietary Ingredient Safety Information.'' This form provides a standard format to describe the history of use or other evidence of safety on which the manufacturer or distributor bases its conclusion that the new dietary ingredient is reasonably expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement, as well as related identity information that is necessary to demonstrate safety by showing that the new dietary ingredient and dietary supplement(s) that are the subject of the notification are the same or similar to the ingredients and products for which safety data and information have been provided. We continue to invite comment on Form FDA 3880 and the supplemental safety information form, which may be found on our website at *https://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/default.htm*.

In the **Federal Register** of November 17, 2017 (82 FR 54355), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. One comment suggested ways FDA might assist respondents by developing ''specific guidance pertaining to the use and submission of master files to help determine whether a dietary ingredient should be the subject of an NDIN or exempted from notification.'' A second comment suggested that FDA: (1) Failed to account for the cost of removing from the market dietary supplements suddenly deemed New Dietary Ingredients for the first time in the Guidance [2]; (2) substantially underestimated the number and cost of New Dietary Ingredient submissions that must be filed to comply with the Guidance; and (3) grossly and dangerously undervalued the economic impact the Guidance will have on the dietary supplement industry and the economy as a whole.

FDA appreciates this feedback. As noted, FDA has issued a draft guidance on Dietary Supplements: New Dietary Ingredient Notifications and Related Issues and will take the comment on additional guidance into consideration when finalizing the draft guidance. As resources allow, FDA may consider revised or additional guidance to assist respondents to the information collection. Relatedly, with regard to comments about costs or economic impact, FDA notes that, consistent with our regulations at 21 CFR part 10.115 (Good Guidance Practices), recommendations found in the draft guidance document are for comment only. In addition, the data analysis proffered regarding costs does not provide a basis upon which we can revise our burden estimate under the PRA. Notices published in the **Federal Register** in compliance with the PRA seek to improve information collection activities by evaluating our need for the information discussed in the notice and specific ways we might utilize technology and/or enhance our collection techniques and mechanisms to minimize burden on respondents who are subject to the applicable regulatory requirements.

We therefore retain the following estimate:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
190.6; Dietary Supplements	55	1	55	20	1,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] The ''Guidance'' refers to a draft guidance published for comment in August 2016 and available at: *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm257563.htm*.

We have made no adjustments to the currently approved burden estimate for the information collection. While we have received comments previously suggesting our burden estimate may be too low, the comments did not discuss the basis for such a conclusion. We therefore specifically invite individual respondent experience with the information collection and associated collection burden.

Based on our experience with the information collection over the past 3 years, we estimate that 55 respondents will submit 1 premarket notification each. We assume that extracting and summarizing relevant information from existing files and presenting it in a format that meets the requirements of § 190.6 will take approximately 20 hours of work per notification. We have carefully considered the burden associated with the premarket notification requirement and believe that estimates greater than 20 hours are likely to include burden associated with researching and generating safety data for a new dietary ingredient. We believe that the burden of the premarket notification requirement on industry is minimal and reasonable because we are requesting only safety and identity information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in compliance with the FD&C Act. Under section 413(a)(2) of the FD&C Act, a dietary supplement that contains a new dietary ingredient is deemed to be adulterated unless there is a history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement. This requirement is separate from and additional to the requirement to submit a premarket notification for the new dietary ingredient. FDA's regulation on new dietary ingredient notifications, § 190.6(a), requires the manufacturer or distributor of the dietary supplement or of the new dietary ingredient to submit to FDA the information that forms the basis for its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. Thus, § 190.6 only requires the manufacturer or distributor to extract and summarize information that should have already been developed to meet the safety requirement in section 413(a)(2) of the FD&C Act.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06155 Filed 3–27–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1184]

Gastrointestinal Drugs Advisory Committee and the Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Gastrointestinal Drugs Advisory Committee and the Pediatric Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on May 3, 2018, from 8 a.m. to 4:30 p.m.

ADDRESSES: DoubleTree by Hilton Hotel Bethesda—Washington DC, Grand Ballroom, 8120 Wisconsin Ave., Bethesda, MD 20814–3624. The conference center's telephone number is 301–652–2000. Answers to commonly asked questions about FDA Advisory Committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* Information about the DoubleTree by Hilton Hotel Bethesda—Washington DC Conference Center can be accessed at: *http://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-hotel-bethesda-washington-dc-WASBHDT/index.html.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–1184. The docket will close on May 2, 2018. Submit either electronic or written comments on this public meeting by May 2, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 2, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of May 2, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before April 19, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–N–1184 for ''Gastrointestinal Drugs Advisory Committee and the Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public