burden estimate to include the methodology or reasoning used to do so.

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 estimate that extracting and summarizing the relevant information from what exists in the company's 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 also 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: November 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24925 Filed 11–16–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0313]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Guidance for Industry, Researchers, Patient Groups, and FDA Staff on Meetings with the Office of Orphan Products Development.

DATES: Submit either electronic or written comments on the collection of information by January 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 16, 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.

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–2014–D–0313 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings with the Office of Orphan Products Development.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development

OMB Control Number 0910–0787—Extension

This information collection supports Agency guidance regarding staff meetings with the Office of Orphan Products Development. Each year, the Office of Orphan Products Development (OOPD) staff participates in meetings with stakeholders who seek guidance or clarification relating to orphan drug or humanitarian use device (HUD) designation requests, OOPD grant programs, or other rare disease issues. These meetings can be ''informal'' or ''formal'' and help build a common understanding on FDA's thoughts on orphan products, which may include drugs, biological products, devices, or medical foods for a rare disease or condition. These meetings may represent critical points in the orphan product development process and may even have an impact on the eventual availability of products for patients with rare diseases and conditions. It is important that these meetings be scheduled within a reasonable time, conducted effectively, and documented where appropriate.

Topics addressed in this guidance include: (1) Clarification of what constitutes an ''informal'' or ''formal'' meeting, (2) program areas within OOPD that may be affected by this draft guidance, (3) procedures for requesting and scheduling meetings with OOPD, (4) description of what constitutes a meeting package, and (5) procedures for the conduct and documentation of meetings with OOPD. This guidance provides consistent procedures to promote well-managed meetings between OOPD and stakeholders.

Burden estimate. Table 1 of this document provides an estimate of the annual reporting burden associated with the recommendation found in the guidance.

Request for a meeting. Based upon information collected from OOPD program areas, approximately 2,332 informal and 51 formal meetings were requested with OOPD in fiscal year (FY) 2016 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of meeting requests and stakeholders will remain the same or will only slightly increase and therefore estimates the total number of meeting requests will be 2,383 annually (2332 informal and 51 formal meetings). The hours per response, which is the estimated number of hours that a stakeholder would spend preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be approximately 3 hours for informal meetings and approximately 10 hours for formal meetings. Based on FDA's experience, the Agency expects that it will take stakeholders this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting. Therefore, the Agency estimates that stakeholders will spend 7,506 hours per year (6,996 hours for informal meetings and 510 hours for formal meetings) preparing meeting requests to OOPD regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Meeting packages. Based upon information collected from OOPD program areas, OOPD held approximately 51 formal meetings in FY 2016 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of formal meetings, and therefore meeting packages, may increase only slightly as a result of this guidance; thus, the Agency estimates that the total responses will be 51 annually. As stated previously, it is current practice for stakeholders to submit meeting packages to the Agency in advance of any such formal meeting. The hours per response, which is the

estimated number of hours that a stakeholder would spend preparing the meeting package in accordance with this guidance, is estimated to be approximately 18 hours. Based on FDA's experience, the Agency expects it will take stakeholders this amount of time to gather and copy brief statements about the product, a description of details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the Agency. Therefore, the Agency estimates that stakeholders will spend 918 hours per year submitting meeting packages to the Agency prior to a formal meeting regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Draft meeting minutes. Based upon information collected from OOPD program areas, OOPD received approximately 51 draft meeting minutes for formal meetings and 23 draft meeting minutes for informal meetings in FY 2016 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of stakeholders submitting draft meeting minutes may remain the same or increase only slightly; thus, the Agency estimates that the total number of respondents will be 74 annually. As stated previously, it is current practice for stakeholders to submit draft meeting minutes to the Agency after all formal meetings and certain informal meetings. The hours per response, which is the estimated number of hours that a stakeholder would spend preparing draft meeting minutes in accordance with this guidance, is estimated to be approximately 8 hours. Based on FDA's experience, the Agency expects it will take stakeholders this amount of time to summarize the meeting discussion points, agreements, disagreements, and action items. Therefore, the Agency estimates that stakeholders will spend 592 hours per year submitting draft meeting minutes to the Agency documenting the meeting outcomes, agreements, disagreements, and action items as followup to all formal and certain informal meetings.

FDA therefore estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Meeting requests, packages and minutes	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting requests (informal)	2,332	1	2,332	3	6,996
Meeting requests (formal)	51	1	51	10	510
Meeting packages	51	1	51	18	918
Meeting minutes	74	1	74	8	592
Total					9,016

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

Since the last OMB approval, we have increased our estimate by 832 hours and 229 respondents in parallel to an increase in overall orphan drug designation submissions and to correspond meeting requests to the Office of Orphan Products Development.

Dated: November 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24926 Filed 11–16–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6175]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA recalls for human drugs, biological products, devices, animal drugs, food, cosmetics, and tobacco.

DATES: Submit either electronic or written comments on the collection of information by January 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 16, 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.

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.*