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]

BILLING CODE 4164–01–P

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.*

• 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–2017–N–6175 for ''Agency Information Collection Activities; Proposed Collection; Food and Drug Administration Recall Regulations.'' 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

FDA Recall Regulations—21 CFR Part 7

OMB Control Number 0910–0249—Extension

Section 701 of the Federal Food, Drug, and Cosmetic Act charges the Secretary of Health and Human Services, through FDA, with the responsibility of assuring recalls (21 U.S.C. 371, Regulations and hearings, and 21 CFR part 7, Enforcement Policy, Subpart C, Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities which pertain to the recall regulations and provide guidance to manufacturers on recall responsibilities). The regulations and guidance apply to all FDA-regulated products (*i.e.,* food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; biological products intended for human use; and tobacco).

These responsibilities of companies conducting recalls include providing FDA with complete details of the recall including: (1) Reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, a copy of any recall communication(s), and a contact official (§ 7.46); (2) notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); and (3) submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluation return reply cards, effectiveness checks and product returns (§ 7.53), and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55(b)).

A search of the FDA database was performed to determine the number of recalls that took place during fiscal years 2014 to 2016. The resulting number of total recalls (8,560) from this database search were then averaged over the 3 years, and the resulting per year average of recalls (2,853) are used in estimating the current annual reporting burden for this report. The resulting number of total terminations (8,560) from this database search were then averaged over the 3 years, and the resulting per year average of terminations (2,853) are used in estimating the current annual reporting burden for this report.

FDA estimates the total annual industry burden to collect and provide the required information to be 470,745 burden hours.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the reporting requirements of FDA's recall regulations, recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products.

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

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	Total hours
Firm initiated recall (§ 7.46) and recall communications (§ 7.49)	2,853	1	2,853	25	71,325
Recall status reports (§ 7.53)	2,853	13	37,089	10	370,890
Termination of a recall (§ 7.55(b))	2,853	1	2,853	10	28,530
Total					470,745

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

I. Total Annual Reporting

A. Firm Initiated Recall and Recall Communications

We request firms that voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices, biologics, and tobacco to immediately notify the appropriate FDA District Office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy, and a contact official as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the Agency estimates it will receive 2,853 responses annually based on the average number of recalls over the last 3 fiscal years. The number of responses multiplied by the number of respondents equals 2,853. The average burden hours, 25, multiplied by total number of annual responses equal 71,325.

B. Recall Status Reports

We request that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This request only applies to firms with active recalls, and periodic status reports are estimated to be reported every 2 to 4 weeks. This collection of information will generate approximately 2,853 responses annually, based on the average number of recalls over the last 3 fiscal years, 8,560. The number of respondents multiplied by the number of responses per respondents (13) equals a total number of annual responses of 37,089. The total number of responses, 37,089, multiplied by an average burden hours of 10 per response equals a total of 370,890 total hours.

C. Termination of a Recall

We provide the firms an opportunity to request in writing that FDA end the recall. The Agency estimates it will receive 2,853 responses annually based on the average number of terminations over the past 3 fiscal years. The total annual responses of 2,853 multiplied by the average burden hours of 10 per response equals a total number of hours of 28,530.

II. Total Annual Third-Party Disclosure Burden

Recall Communications. We request that firms notify their consignees of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under this portion of the collection of information, the Agency estimates firms will provide 4,433,562 notifications annually based on the number of respondents/consignees (2,853) multiplied by the number of disclosures per respondent (1,554). The total number of hours is 248,279 (based on 4,433,562 multiplied by 0.056 hours).

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recall communications (§ 7.49)	2,853	1,554	4,433,562	0.056	248,279

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

FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. FDA notes that not all third-party disclosures provided by firms to their consignees are similar in nature and may entail different methods and mediums of communication. FDA estimates the burden for third-party disclosure per recall event to be an average of 25 hours. This burden estimate factored out to the average number of consignees per recall (1,554) results in a burden per disclosure estimate of approximate hours (25 hours per recall/1,554 disclosures/recall = 0.056 hours).

Dated: November 9, 2017.

Anna K. Abram,

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

[FR Doc. 2017–24923 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–6152]

Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Zika Virus; Availability

AGENCY: Food and Drug Administration, HHS.