and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss new drug application (NDA) 209229, lofexidine hydrochloride, submitted by US WorldMeds, LLC, for mitigation of symptoms associated with opioid withdrawal and facilitation of completion of opioid discontinuation treatment.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the docket (see **ADDRESSES**) on or before March 13, 2018, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 5, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 6, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Kalyani Bhatt (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03808 Filed 2–23–18; 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; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Recall Regulations

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.

DATES: Fax written comments on the collection of information by March 28, 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 0910–0249. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

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 and terminations (8,560) from this database search were then averaged over the 3 years, and the resulting per year average of recalls and terminations (2,853) are used in estimating the current annual reporting and third party disclosure burden in this notice.

FDA estimates, in the following tables, the total annual reporting and third party burden to collect and provide the required information to be 584,477 hours.

In the **Federal Register** of November 17, 2017 (82 FR 54359), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment that did not suggest any changes to the information collection or burden estimates.

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, this summary reflects numbers across FDA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/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
General industry guidance (§ 7.59)	2,853	1	2,853	15	42,795
Total					513,540

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

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. The estimates in table 1 are multiplied across the FDA product centers to arrive at a reporting burden estimate of 71,325 for firm initiated recall and recall communications.

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. The estimates in table 1 are multiplied across the FDA product centers to arrive at a reporting burden estimate of 370,890 hours for recall status reports.

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 estimates in table 1 are multiplied across the FDA product centers to arrive at a reporting burden estimate of 28,530 for termination of a recall.

D. Enforcement Policy

We request that firms prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§ 7.40 through 7.49, 7.53, and 7.55; use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots and maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention. The estimates in table 1 are multiplied across the FDA product centers to arrive at a reporting burden estimate of 42,795 for enforcement policy.

E. 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.

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

Activity/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	518	1,477,854	0.048 (2.88 minutes)	70,937

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

The estimates in table 2 are multiplied across the FDA product centers to arrive at a total third party disclosure burden estimate of 70,937.

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. The total burden hours have decreased since the last information collection approval based on a reduction in the number of respondents.

Dated: February 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03847 Filed 2–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0510]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed

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.

DATES: Fax written comments on the collection of information by March 28, 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 0910–0627. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Substances Prohibited From Use in Animal Food or Feed—21 CFR 589.2001

OMB Control Number 0910–0627—Extension

This information collection supports Agency regulations regarding substances prohibited from use in animal food or feed. Bovine spongiform encephalopathy (BSE) is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. Our regulation at § 589.2001 (21 CFR 589.2001) entitled ''Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy'' is designed to further strengthen existing safeguards against the establishment and amplification of BSE in the United States through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials are referred to as ''cattle materials prohibited in animal feed'' or CMPAF. Under § 589.2001, no animal feed or feed ingredient can contain CMPAF. As a result, we impose requirements on renderers of specifically defined cattle materials, including reporting and recordkeeping requirements. For purposes of the regulation, we define a renderer as any firm or individual that processes slaughter byproducts, animals unfit for human consumption, including carcasses of dead cattle, or meat scraps. Reporting and recordkeeping requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know whether the cattle material meets the requirements of our regulation.

Recordkeeping: Renderers that receive, manufacture, process, blend, or distribute CMPAF, or products that contain or may contain CMPAF, must take measures to ensure that the materials are not introduced into animal feed, including maintaining adequate written procedures specifying how such processes are to be carried out (§ 589.2001(c)(2)(ii)). Renderers that receive, manufacture, process, blend, or distribute CMPAF, are required to establish and maintain records sufficient to track the CMPAF to ensure that they are not introduced into animal feed (§ 589.2001(c)(2)(vi)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, CMPAF (§ 589.2001(c)(3)(i)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must, if these materials were obtained from an establishment that segregates CMPAF from other materials, establish and maintain records to demonstrate that the supplier has adequate procedures in place to effectively exclude CMPAF from any materials supplied (§ 589.2001(c)(3)(i)). Records will meet this requirement if they include either: (1) Certification or other documentation from the supplier that materials supplied do not include CMPAF (§ 589.2001(c)(3)(i)(A)) or (2) documentation of another method acceptable to FDA, such as third-party certification (§ 589.2001(c)(3)(i)(B)).

Reporting: Under our regulations, we may designate a country from which cattle materials are not considered CMPAF. Section 589.2001(f) provides that a country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine. The information the country is required to submit includes information about that country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in § 589.2001(b)(1). We use the information to determine whether to grant a request for designation and to impose conditions if a request is granted. Section 589.2001(f) further states that countries designated under that section will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries from time to time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We may revoke a country's designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to our periodic requests by