FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 5 years.

Dated: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18302 Filed 8–1–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1031]

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) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 October 3, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 Regulation—21 CFR Part 7 (OMB Control Number 0910–0249)—Extension

Section 701 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) charges the Secretary of Health and Human Services (HHS), through the 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 guidelines 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 include providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, the firm's recall strategy, a copy of any recall communication(s), and a contact official (§ 7.46); 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 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 FDA's database was performed to determine the number of recalls that took place during fiscal years 2011 to 2013. The resulting number of total recalls (11,403) from this database search were then averaged over the 3 years, and the resulting per year average of recalls (3,801) are used in estimating the current annual reporting burden for this report. The resulting number of total terminations (11,403 from this database search were then averaged over the 3 years, and the resulting per year average of terminations (3,801 are used in estimating the current annual reporting burden for this report.

FDA estimates the total annual industry burden to collect and provide the previous information to be 627,165 burden hours.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the voluntary 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]

Recall	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Firm Initiated Recall (21 CFR 7.46) and Recall Communications (21 CFR 7.49)	3,801	1	3,801	25	95,025
Recall Status Reports (21 CFR 7.53)	3,801	13	49,413	10	494,130
Termination of a Recall (21 CFR 7.55(b))	3,801	1	3,801	10	38,010
Total					627,165

[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

Request firms 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 3,801 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 equal 3,801. The average burden hours of 25 multiplied by the total number of annual responses equal 95,025. The average burden hour person response was 30 and has decreased by 5.

B. Recall Status Reports

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 is estimated to be reported every 2 to 4 weeks. This collection of information will generate approximately 3,801 responses annually, based on the average number of recalls over the last 3 fiscal years 11,403. The number of respondents multiplied by the number of responses per respondents (13) equal a total number of annual responses of 49,413. The total number of responses 49,413 with an average burden hours of 10 per response equal a total of 494,130 total hours.

C. Termination of a Recall

Provide the firms an opportunity to request in writing that FDA end the recall. The Agency estimates it will receive 3,801 responses annually based on the average number of terminations over the past 3 fiscal years. The total annual responses of 3,801 multiplied by the average burden hours of 10 per response equal a total number of hours of 38,010.

II. Hours per Response Estimates

FDA has no information which would allow it to make a calculated estimate on the hours per response burden to FDA regulated firms to conduct recalls. Variables in the type of products, the quantity and level of distribution and the various circumstances of recall notifications could cause the hours per response to vary significantly. The best guesstimate of average burden hours per response from previous information collection request reports are utilized again for the current estimates on burden hours per response.

Dated: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18322 Filed 8–1–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 11, 2014, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College, Potomac Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301–985–7300.

Contact Person: Karen Abraham-Burrell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2147, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *EMDAC@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 Agency's Web site at *http://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.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 206321, liraglutide for injection, sponsored by Novo Nordisk, Inc. The proposed indication for liraglutide is as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kilograms per square meter (kg/m^2) or greater, or with an initial BMI of 27 kg/m^2 or greater in the presence of at least one weight-related comorbidity.

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 Web site prior to the meeting, the background material will