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]

BILLING CODE 4164–01–P

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

be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://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. Written submissions may be made to the contact person on or before August 27, 2014. 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 August 19, 2014. 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 August 20, 2014.

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

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Abraham-Burrell at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://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: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18304 Filed 8–1–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Management Grant Program; Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on July 3, 2014, for the FY 2014 Tribal Management Grant Program Announcement. Key information pertaining to Funding Restrictions was omitted.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Spotted Horse, Program Analyst, Office of Direct Service and Contracting Tribes, Indian Health Service, 801 Thompson Avenue, Suite 220, Rockville, MD 20852, Telephone (301) 443–1104. (This is not a toll-free number.)

Corrections

In the **Federal Register** of July 3, 2014, in FR Doc. 2014–15595, on page 38043, in the second column, under the heading 5. Funding Restrictions after the fourth bullet, the following language regarding Restrictions should be added:

- The TMG may not be used to support recurring operational programs or to replace existing public and private resources. Funding received under a recurring Public Law 93–638 contract cannot be totally supplanted or totally replaced. Exception is allowed to charge a portion or percentage of salaries of existing staff positions involved in implementing the TMG grant, if applicable. However, this percentage of TMG funding must reflect supplementation of funding for the project not supplantation of existing ISDEAA contract funds. Supplementation is ''adding to a program'' whereas supplantation is ''taking the place of'' funds. An entity cannot use the TMG funds to supplant the ISDEAA contract or recurring funding.
- Ineligible Project Activities—The inclusion of the following projects or activities in an application will render the application ineligible.
  - Planning and negotiating activities associated with the intent of a Tribe to enter the IHS Self-Governance Project. A separate grant program is administered by the IHS for this purpose. Prospective applicants interested in this program should contact Mrs. Anna Johnson, Program Analyst, Office of Tribal Self-Governance, Indian Health Service, Reyes Building, 801 Thompson Avenue, Suite 240, Rockville, Maryland 20852, (301) 443–7821, and request information concerning the ''Tribal Self-Governance Program Planning Cooperative Agreement Announcement'' or the ''Negotiation Cooperative Agreement Announcement.''
  - Projects related to water, sanitation, and waste management.
  - Projects that include direct patient care and/or equipment to provide those medical services to be used to establish or augment or continue direct patient clinical care. Medical equipment that is allowable under the Special Diabetes Grant Program is not allowable under the TMG Program.
  - Projects that include recruitment efforts for direct patient care services.
  - Projects that include long-term care or provision of any direct services.
  - Projects that include tuition, fees, or stipends for certification or training of staff to provide direct services.
  - Projects that include pre-planning, design, and planning of construction for facilities, including activities relating to program justification documents.
  - Projects that propose more than one project type. Refer to Section II, ''Award Information,'' specifically ''Eligible TMG Project Types, Maximum Funding Levels and Project Periods'' for more information. An example of a proposal with more than one project type that would be considered ineligible may include the creation of a strategic health plan (defined by TMG as a planning project type) and improving third-party billing structures (defined by TMG as a health management structure project type). Multi-year applications that include in the first year planning, evaluation, or feasibility activities with the remainder of the project years addressing management structure are also deemed ineligible.
- Other Limitations—A current TMG recipient cannot be awarded a new, renewal, or competing continuation grant for any of the following reasons:
  - The grantee will be administering two TMGs at the same time or have overlapping project/budget periods;
  - The current project is not progressing in a satisfactory manner;
  - The current project is not in compliance with program and financial reporting requirements; or
  - The applicant has an outstanding delinquent Federal debt. No award shall be made until either: