TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Federal Food, Drug, and Cosmetic Act or 21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 412(d) of the FD&C Act	5	13	65	10	650
21 CFR 106.120(b)	1	1	1	4	4
21 CFR 107.50(b)(3) and (b)(4)	3	2	6	4	24
21 CFR 107.50(e)(2)	1	1	1	4	4
Total					682

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
106.100	5	10	50	400	20,000
107.50(c)(3)	3	10	30	300	9,000
Total					29,000

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

TABLE 3—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
21 CFR 107.10(a) and 107.20	5	13	65	8	520

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

In compiling these estimates, we consulted our records of the number of infant formula submissions received in the past. All infant formula submissions may be provided to us in electronic format. The hours per response reporting estimates are based on our experience with similar programs and information received from industry.

We estimate that we will receive 13 reports from 5 manufacturers annually under section 412(d) of the FD&C Act, for a total annual response of 65 reports. Each report is estimated to take 10 hours per response for a total of 650 hours. We also estimate that we will receive one notification under § 106.120(b). The notification is expected to take four hours per response, for a total of four hours.

For exempt infant formula, we estimate that we will receive 2 reports from 3 manufacturers annually under §§ 107.50(b)(3) and (b)(4), for a total annual response of 6 reports. Each report is estimated to take 4 hours per response for a total of 24 hours. We also estimate that we will receive one notification annually under § 107.50(e)(2) and that the notification will take 4 hours to prepare.

We estimate that 5 firms will expend approximately 20,000 hours per year to fully satisfy the recordkeeping requirements in § 106.100 and that 3 firms will expend approximately 9,000 hours per year to fully satisfy the recordkeeping requirements in § 107.50(c)(3).

We estimate compliance with our labeling requirements in §§ 107.10(a) and 107.20 requires 520 hours annually by 5 manufacturers.

Dated: September 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–24046 Filed 10–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Vaccines and Related Biological Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products 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 November 13, 2013, between approximately 12:30 p.m. and 3:45 p.m.

Location: Rockwall II, Conference Room 1033, 5515 Security Lane, Rockville, MD 20852. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room.

Contact Person for More Information: Donald W. Jehn or Denise Royster, Food and Drug Administration, 1401 Rockville Pike (HFM–71), Rockville, MD 20852, 301–827–0314, 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: On November 13, 2013, the committee will meet in open session to hear an overview of the research programs in the Laboratory of Retroviruses and Laboratory of Immunoregulation, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Review, FDA.

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: On November 13, 2013, from 12:30 p.m. to approximately 3:10 p.m., the meeting is open to the public. 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 November 6, 2013. Oral presentations from the public will be scheduled between approximately 2:10 p.m. and approximately 3:10 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 October 29, 2013. 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 October 30, 2013.

Closed Committee Deliberations: On November 13, 2013, between approximately 3:10 p.m. and approximately 3:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

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 Donald W. Jehn or Denise Royster 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: September 26, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–24025 Filed 10–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Notice Request: Application Process for Clinical Research Training and Medical Education at the Clinical Center and Its Impact on Course and Training Program Enrollment and Effectiveness

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed application information collection, the Clinical Center (CC), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Robert M. Lembo, MD, Deputy Director, Office of Clinical Research Training and Medical Education, NIH Clinical Center, 10 Center Drive, MSC 1158, Bethesda, MD 20892–1352, or call non-toll-free number (301)–594–4193, or Email your request, including your address to: *lembor@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Application Process for Clinical Research Training and Medical Education at the Clinical Center and its Impact on Course and Training Program Enrollment and Effectiveness, 0925–NEW, Clinical Center, National Institutes of Health (CC), National Institutes of Health (NIH).

Need and Use of Information Collection: The primary objective of the application process is to allow OCRTME to evaluate applicants' qualifications to determine applicants' eligibility for courses and training programs managed by the office. Applicants must provide the required information requested in the respective applications to be considered a candidate for participation. Information submitted by candidates for training programs is reviewed initially by OCRTME administrative staff to establish eligibility for participation. Eligible candidates are then referred to the designated training program director or training program selection committee for review and decisions regarding