

interactions for a broad range of carefully classified birth defects.

This request is submitted to revise the previously estimated burden details and

to request OMB clearance for three additional years. The total estimated annual burden hours are 3,034.

There are no costs to the respondents other than their time.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Respondents	Activity	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Mothers (interview)	Telephone consent and BD-STEPS questionnaire.	2,365	1	45/60	1,774
Mothers (consent for bloodspot retrieval).	Written consent for bloodspot retrieval.	1,375	1	15/60	344
Mothers (online occupational questionnaire).	Online Occupational Questionnaire	790	1	20/60	263
Mothers (consent for medical records review).	Written release for medical records review.	475	1	15/60	119
Records reviewers (medical records review).	Pulling and sending records	475	1	30/60	238
Mothers of all AR/MA stillbirths and controls (supplemental telephone interview).	Telephone consent and supplemental questionnaire.	710	1	25/60	296
Total	3,034

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016-05949 Filed 3-16-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 8:30 a.m.–3:00 p.m., EDT, April 21, 2016.

Place: CDC, Building 19, Global Communications Center, Auditorium B3, 1600 Clifton Road NE., Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space and phone lines available. The meeting room accommodates approximately 50 people. Advance registration for in-person participation is required by April 7, 2016. The public is welcome to participate during the public comment period, which is tentatively scheduled from 2:40 p.m. to 2:45 p.m. This meeting will also be available by

teleconference. Please dial (877) 930-8819 and enter code 1579739.

Web links:

Windows Media: <http://wm.onlinevideosevice.com/CDC1>.

Flash: <http://www.onlinevideosevice.com/clients/CDC/?mount=CDC3>.

Smart Phone and Mobile Devices:

<http://wowza01.sea.onlinevideosevice.com/live/CDC3/playlist.m3u8>.

If you are unable to connect using the link, copy and paste the link into your web browser. For technical support please call: (404) 639-3737.

Purpose: The Advisory Committee to the Director, CDC, shall advise the Secretary, HHS, and the Director, CDC, on policy and broad strategies that will enable CDC to fulfill its mission of protecting health through health promotion, prevention, and preparedness. The committee recommends ways to prioritize CDC's activities, improve results, and address health disparities. It also provides guidance to help CDC work more effectively with its various private and public sector constituents to make health protection a practical reality.

Matters for Discussion: The Advisory Committee to the Director will receive updates from the State, Tribal, Local and Territorial Subcommittee; the Health Disparities Subcommittee, the Ethical Considerations for Public Private Partnerships Workgroup, the Global Workgroup, the Internal and External Laboratory Safety Workgroups, and the Public Health—Health Care

Collaboration Workgroup, as well as an update from the CDC Director.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Carmen Villar, MSW, Designated Federal Officer, ACD, CDC, 1600 Clifton Road NE., M/S D-14, Atlanta, Georgia 30329. Telephone (404) 639-7037, Email: xjj4@cdc.gov. The deadline to register for in-person attendance at this meeting is April 7, 2016. To register, please send an email to xjj4@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-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 May 25, 2016, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: LaToya Bonner, 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, 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) 208583 for insulin degludec and liraglutide injection, submitted by Novo Nordisk Inc., for the proposed indication: Adjunct to diet and exercise to improve glycemic control in the treatment of adults with type 2 diabetes mellitus.

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 May 10, 2016. 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 May 2, 2016. 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 May 3, 2016.

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 LaToya Bonner 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: March 11, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management 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 Committees: Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

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

Date and Time: The meeting will be held on June 7, 2016, from 8 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Stephanie L. Begansky, 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: AADPAC@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>