

Study Section business and for the study section to consider safety and occupational health-related grant applications.

For Further Information Contact: Nina Turner, Ph.D., Scientific Review Officer, NIOSH, 1095 Willowdale Road, Morgantown, WV 26506, (304) 285-5976; nturner@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.

[FR Doc. 2017-27165 Filed 12-15-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC); Notice of Charter Renewal; Correction

Notice is hereby given of a change in the Charter Renewal of the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC), Notice of Charter Renewal which was published in the **Federal Register** on November 24, 2017, Volume 82, Number 225, page 55843.

The name of the committee should read as follows: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC) and the Summary section should read as follows:

SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through November 5, 2019.

FOR FURTHER INFORMATION CONTACT:

Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F-63, Atlanta, GA 30341, Telephone (770) 488-1430. Email address: GCattledge@cdc.gov.

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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

Centers for Disease Control and Prevention

Invitation to Manufacturers of Pertussis Serological Kits

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces an opportunity for commercial manufacturers to work with CDC's National Center for Immunization and Respiratory Diseases (NCIRD) on the validation of pertussis serological kits prior to submission to the Food and Drug Administration (FDA) for marketing authorization. CDC is interested in the development of an assay that is an Immunoglobulin G (IgG) anti-pertussis toxin (PT) enzyme-linked immunosorbent assay (ELISA), calibrated to an international reference standard (such as FDA Reference Standard Lot #3, World Health Organization (WHO) International Standard 06/140, or equivalents). The ELISA will be used for *in vitro* serological diagnosis of pertussis in clinical cases of selected age groups. CDC will be able to provide guidance, materials, and evaluation support for the manufacturer; however, the manufacturer will be responsible for submitting a premarket submission to FDA with adequate information, including any analytical or clinical data needed to support the submission, to demonstrate to FDA that FDA can grant marketing authorization to the product.

DATES: CDC is accepting information through June 18, 2018.

ADDRESSES: You may submit information by any of the following methods:

- *Email:* PertussisDL@cdc.gov.
- *Mail:* Lucia Tondella, National Center for Immunization and

Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop D-11, Atlanta, GA 30329.

FOR FURTHER INFORMATION CONTACT:

For Technical Questions: Lucia Tondella, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop D-11, Atlanta, GA 30329. Phone: 404-639-1239, Email: PertussisDL@cdc.gov.

For Business Questions: Jason Cloward, Technology Transfer Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop E-51, Atlanta, GA 30329. Phone: 404-639-2679, Email: wvn3@cdc.gov.

SUPPLEMENTARY INFORMATION: CDC's National Center for Immunization and Respiratory Diseases (NCIRD), Division of Bacterial Diseases (DBD), Meningitis and Vaccine Preventable Diseases Branch (MVPDB) has lead technical responsibility for research, development and evaluation of diagnostic assays for their application in epidemiologic studies of pertussis. CDC uses epidemiologic, laboratory, clinical, and biostatistical sciences to control and prevent bacterial infectious disease such as pertussis. CDC also conducts applied research in a variety of settings, and translates the findings of this research into public health practice.

CDC is working closely with the Council of State and Territorial Epidemiologists (CSTE) to consider including serology as an appropriate diagnostic tool for confirming a pertussis case. Serology can be very useful for diagnosing pertussis in adolescents and adults during the later phases of disease when the current accepted diagnostic methods, culture and PCR, are no longer reliable. Sensitive and specific quantitative seroassays have been developed and are routinely used for diagnosis of pertussis world-wide; however, FDA marketing authorization is necessary before these seroassays can be made commercially available as *in vitro* diagnostics in the United States. To date, no quantitative pertussis serology kits are commercially available in the United States for diagnostic use.

Interested manufacturers that may have candidate products are invited to contact CDC to discuss potential opportunities for collaboration. At a minimum, discussions with CDC should include the following information for each candidate product:

- a. Product package insert or detailed instructions for use.

b. Detailed information to determine if the product is calibrated to a recognized standard.

c. Detailed summary of data demonstrating suitable analytical and clinical test characteristics (*i.e.* precision, linearity, accuracy, sensitivity/specificity, etc.).

Any collaborations that result from these conversations will require that manufacturers enter into an appropriate agreement prior to the transfer of any material to or from CDC. Sample agreements may be viewed at the following website: <https://www.cdc.gov/od/science/technology/techtransfer/researchers/formagreements/index.htm>.

All information submitted to CDC will be kept confidential as allowed by relevant federal law, including the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905).

Dated: December 13, 2017.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2017-27189 Filed 12-15-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6752]

Information Requests and Discipline Review Letters Under the Generic Drug User Fee Amendments; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Information Requests and Discipline Review Letters Under GDUFA.” This draft guidance explains how FDA will issue and use an information request (IR) and/or a discipline review letter (DRL) during the review of an original abbreviated new drug application (ANDA).

DATES: Submit either electronic or written comments on the draft guidance by February 16, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-D-6752 for “Information Requests and Discipline Review Letters Under GDUFA.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states

“THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Philip Bonforte, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1668, Silver Spring, MD 20993-0002, 240-402-9871, philip.bonforte@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Information Requests and Discipline Review Letters Under GDUFA.”

Under the first iteration of the Generic Drug User Fee Amendments of 2012