



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1999-D-1315 (formerly 1999-D-0296)]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants of Prescription Drug User Fee Act (PDUFA) Products.” This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of drug or biological products (“products”). This draft guidance revises the guidance for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants” published May 19, 2009.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillendale Bldg., 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rachel E. Hartford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6312, Silver Spring, MD 20993-0002, 301-796-0319; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.” This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of products regulated by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. This draft guidance does not apply to abbreviated

new drug applications, applications for biosimilar biological products, or submissions for medical devices. For the purposes of this draft guidance, “formal meeting” includes any meeting that is requested by a sponsor or applicant following the request procedures provided in this guidance and includes meetings conducted in any format (i.e., face to face, teleconference, videoconference, or written response).

This draft guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing for, scheduling, conducting, and documenting such formal meetings. The general principles in this draft guidance may be extended to other nonapplication-related meetings with external constituents, insofar as this is possible.

This draft guidance revises the guidance for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants” published May 19, 2009. This draft guidance is being updated in accordance with the Meeting Management Goals section of the PDUFA Reauthorization Performance Goals and Procedures, Fiscal Years 2013 through 2017. Significant changes from the 2009 guidance include:

- Addition of the written response meeting format for pre-investigational new drug application and Type C meetings
- Designation of a post-action meeting requested within 3 months after an FDA regulatory action other than approval as a Type A meeting
- Designation of a post-action meeting requested 3 or more months after an FDA regulatory action other than approval as a Type B meeting

- Designation of a meeting regarding risk evaluation and mitigation strategies or postmarketing requirements that occur outside the context of the review of a marketing application as a Type B meeting
- Inclusion of a meeting package in Type A meeting requests
- Designation of meetings to discuss the overall development program for products granted breakthrough therapy designation status as a Type B meeting

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on formal meetings between FDA and sponsors or applicants of PDUFA products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information referred to in the guidance entitled "Formal Meetings Between the FDA and Sponsors or Applicants" have been approved under OMB control number 0910-0429. The collections of information for Form FDA 1571 and end-of-phase 2 meetings have been approved under OMB control number 0910-0014, and collections of information for Form FDA 356h have been approved under OMB control number 0910-0338.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: March 5, 2015.

Leslie Kux,

Associate Commissioner for Policy,