Dated: September 14, 2009.

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Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0514]

Guidance for Industry on End-of-Phase 2A Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''End-of-Phase 2A Meetings.'' This guidance provides information on end-of-phase 2A (EOP2A) meetings for sponsors of investigational new drug applications (INDs). The purpose of an EOP2A meeting is to facilitate interaction between FDA and sponsors who seek guidance related to clinical trial design employing clinical trial simulation and quantitative modeling of prior knowledge (*e.g.*, drug, disease, placebo), designing trials for better dose response estimation and dose selection, and other related issues. This guidance is intended to further FDA initiatives directed at identifying opportunities to facilitate the development of innovative medical products and improve the quality of drug applications through early meetings with sponsors.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jogarao Gobburu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3186, Silver Spring, MD 20993–0002, 301–796–2460.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''End-of-Phase 2A Meetings.'' This guidance will meet one of the performance goals agreed to under the September 27, 2007, reauthorization of the Prescription Drug User Fee Act (PDUFA IV). Under section XI of the PDUFA IV Performance Goals, Expediting Drug Development, FDA agreed to publish by the end of fiscal year 2008 a draft guidance on EOP2A meetings and to complete the final guidance within 1 year of the close of the public comment period (*see http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm* at section XI.A).

FDA has a long-standing interest in defining dose or exposure-response relationships for the effectiveness and safety of new drugs. Accurate dose-response information is important for understanding how patients should take drugs to maximize desirable effects and minimize undesirable effects. Dose selection for phase 2 and phase 3 studies is a challenge in many drug development programs and poor choice may lead to trial failure. Improving early dose selection may increase the likelihood of future trial success. FDA recognizes trial planning may be improved by clinical trial simulations that employ quantitative models of drug exposure-response, placebo effect, and disease progression. This guidance on EOP2A meetings is intended to encourage the best use of this science to facilitate the exploration of trial design alternatives to increase the likelihood for successful trials.

In the **Federal Register** of September 26, 2008 (73 FR 55851), FDA announced the availability of a draft guidance of the same title. In response to public comments on the draft version, the guidance has been revised to clarify the following topics: (1) The type of information that should be submitted with the meeting request and the background package and (2) the role of the Office of New Drugs in preparing for and conducting EOP2A meetings.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the roles of model-based drug development together with early interaction between FDA and industry to improve late phase clinical trial success. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 in 21 CFR part 312 and the guidance on ''Formal Meetings with Sponsors and Applicants for PDUFA Products'' have been approved under OMB control numbers 0910–0014 and 0910–0429, respectively.

IV. Electronic Access

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

Dated: September 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections