

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0514]

Draft Guidance for Industry on End-of-Phase 2A Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DDM  
Display Date 9-25-08  
Publication Date 9-26-08  
Certifier Stella

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “End-of-Phase 2A Meetings.” This draft guidance provides information on end-of-phase 2A (EOP2A) meetings for sponsors of investigational new drug applications (INDs) who seek guidance on employing clinical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 This draft guidance is intended to further FDA initiatives directed at identifying opportunities to facilitate the development of innovative medical products and to improve the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

**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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research,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, 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Robert Powell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4526, Silver Spring, MD 20993-0002, 301-796-1589.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “End-of-Phase 2A Meetings.” This draft 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 end-of-phase 2A meetings (see section XI.A.4 at <http://www.fda.gov/oc/pdufa4/pdufa4goals.html>). This draft guidance is intended to facilitate early meetings (referred to as end-of-phase 2A meetings or EOP2A meetings) between FDA and sponsors who seek interaction or guidance related to the use of quantitative drug development methods (i.e., exposure-response, pharmacokinetic/pharmacodynamic (PK/PD) modeling, drug-disease modeling, genomic analysis) to inform drug development and regulatory decisions. The

draft guidance provides recommendations to IND sponsors on the following topics:

- Objectives of an EOP2A meeting,
- Possible topics for discussion at EOP2A meetings,
- Useful information for an EOP2A meeting package, and
- Timing of EOP2A meetings.

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 end-of-phase 2A meetings. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

### **III. Paperwork Reduction Act of 1995**

This draft 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/cder/guidance/index.htm> or <http://www.regulations.gov>.

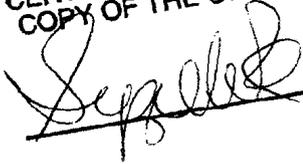
Dated: 9/22/08  
September 22, 2008.

  
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Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

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