DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0122]

Guidance for Industry on Exploratory Investigational New Drug Studies; 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 ''Exploratory IND Studies.'' This guidance describes the preclinical and clinical issues as well as chemistry, manufacturing, and controls information that should be considered when planning exploratory studies, including studies of closely related drugs or biologics, under an investigational new drug (IND) application.

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 (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5346.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Exploratory IND Studies.'' In its March 2004, Critical Path Report,[1] the agency explained that to reduce the time and resources expended during early drug development on candidates that are unlikely to succeed,[2] tools are needed to allow developers to distinguish earlier in the process those candidates that hold promise from those that do not. This guidance describes some exploratory approaches that will protect human subjects while providing early information about candidate performance in humans.

Exploratory IND studies have a number of different goals. In some cases, an exploratory study can help developers gain an understanding of the relationship between a specific mechanism of action and the treatment of a disease. In other cases, a study can provide important information on pharmacokinetics, including, for example, biodistribution of a candidate drug. Whatever the goal of the study, exploratory IND studies can help sponsors identify, early in the process, promising candidates for continued development.

Existing regulations allow a great deal of flexibility in terms of the amount of data that need to be submitted in an IND application, depending on the

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[1]Food and Drug Administration, ''Innovation or Stagnation, Challenge and Opportunity on the critical Path to New Medical Products,'' March 2004.

[2]A new medical compound entering phase 1 testing, often representing the culmination of upwards of a decade of preclinical screening and evaluation, is estimated to have only an eight percent chance of reaching the market, ''Critical Path Report,'' March 2004.

goals of an investigation, the specific human testing being proposed, and the expected risks. But sponsors have not always taken advantage of that flexibility, and limited, early phase 1 studies, such as those described in this guidance, are often supported by a more extensive preclinical database than is needed.

This guidance applies to exploratory studies (i.e., early phase 1 clinical studies), involving IND and biological products, that assess feasibility for further development of a drug or biological product.[3] For the purposes of this guidance the phrase ''exploratory study'' is intended to describe clinical trials that occur very early in phase 1, involve very limited human exposure, and often have no therapeutic or diagnostic intent.

Typically, these exploratory studies are conducted prior to the traditional dose evaluation, safety, and tolerance studies that ordinarily initiate a clinical drug development program. The amount and type of preclinical information necessary to support an exploratory study will depend on the planned nature and extent of human exposure relative to the toxicity (or lack thereof) at the planned dose. The studies discussed in this guidance ordinarily do not have therapeutic intent. They are designed to evaluate whether a particular candidate should be entered into a drug development program.

FDA published a notice in the **Federal Register** of April 14, 2005 (70 FR 19764), announcing the availability of a draft version of this guidance. The agency was interested in soliciting input on the draft guidance. The comment period closed on July 13, 2005. A number of comments were received on the draft, and the agency considered them very carefully during finalization of the

[3]This guidance applies to drug and certain well-characterized therapeutic biological products (e.g., recombinant therapeutic proteins and monoclonal antibodies regulated by the Center for Drug Evaluation and Research). The guidance does not apply to human cell or tissue products, blood and blood proteins, vaccines, or to products regulated as devices.

guidance. A number of clarifying changes were made during finalization of the guidance, but substantive changes were not made.

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 exploratory IND studies. 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. 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 collection of information has been approved under OMB control number 0910–0014.

III. 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.

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.fda.gov/ohrms/dockets/default.htm*.

Dated: January 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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