

facilitated should questions regarding their medical procedures arise?

Best practices identified through the analyses of interview data could lead to the development of standardized procedures to: (a) Reduce secondary exposure to radiation by members of the patient's family and by the public; and (b) ensure that patients who activate radiation detectors at security checkpoints understand why they emit radiation and carry the appropriate documentation to validate their statements. The study findings will be disseminated to the health care community through a scholarly publication journal article (title is to be determined).

**Data Confidentiality Provisions**

Data collected by the contractor and the contractor's draft analyses will be retained for one year after final acceptance of all contract deliverables, unless, longer retention is requested by the agency for audit purposes.

All agency documents pertaining to the contract will be archived after the contract is completed and retained in accordance with a Federal Records Act of 1950 retention schedule.

**Methods of Collection**

The data will be collected using a telephone survey. The contractor will contact each health provider through appropriate management offices explaining this survey and ask to be directed to the appropriate, knowledgeable staff in their facility. The interviews will be conducted by telephone. If requested, the contractor will provide a copy of the interview questions in advance so that the hospital staff has time to obtain pertinent information. The contractor will also request copies of educational materials provided to patients, any specific tools used to calculate radiation dose to members of the public as well as other pertinent material. The contractor will obtain and evaluate the

referenced educational materials qualitatively, describing the content and detail of such materials and reviewing them for clarity. In addition, the contractor will analyze the responses to the interview questions quantitatively and qualitatively as appropriate.

To recruit the appropriate interviewees, we will first contact the Chief of medicine's office and ask the staff to refer us to the Head of the Department of Radiology/Radiation Oncology/Nuclear Medicine. (Based on our experience surveying health care providers, for smaller hospitals it is sometimes more effective to start with the Hospital Administrator's office.) We will introduce ourselves, explain the goals of the study, and volunteer to provide a cover letter describing the study and any letters of endorsement. We will then contact the Department Heads and request that they refer us to the appropriate, knowledgeable staff in their departments.

**Estimated Annual Respondent Burden**

Type of survey	Number of respondents	Estimated time per respondent in minutes	Estimated total burden hours	Estimated annual cost to the respondents
Telephone interviews .....	60	45	45	\$4500
Total .....	60	45	45	4500

**Request for Comments**

In accordance with the above cited legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of AHRQ, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: January 6, 2006.

**Carolyn M. Clancy,**  
Director.

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**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,<sup>1</sup> the agency explained that to reduce the time and resources expended during early drug development on candidates that are unlikely to succeed,<sup>2</sup> 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 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.<sup>3</sup> 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,

<sup>1</sup>Food and Drug Administration, “Innovation or Stagnation, Challenge and Opportunity on the critical Path to New Medical Products,” March 2004.

<sup>2</sup>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.

<sup>3</sup>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.

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 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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D–0286]

#### Draft Guidance for Industry on Investigational New Drugs; Approaches to Complying with Current Good Manufacturing Practice During Phase 1; 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 “INDs—Approaches to Complying with CGMP During Phase 1.” This draft guidance is intended to assist persons producing drug and biological products (investigational drugs) for use during phase 1 development in complying with relevant current good manufacturing practice (CGMP) as required by the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Controls for producing an investigational new drug (IND) for use in a phase 1 study are primarily aimed at ensuring subject safety. This guidance is being issued concurrently with a direct final rule and companion proposed rule published elsewhere in this issue of the **Federal Register**, which, if finalized, will specify that the particular requirements in the regulations need not be met for most investigational drugs manufactured for use during phase 1 development. Instead, the agency recommends the approaches outlined in this guidance for complying with the FD&C Act.

**DATES:** Submit written or electronic comments on the draft guidance by March 20, 2006. General comments on agency guidance documents are welcome at any time.