DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0125]

Draft Guidance for Industry and Researchers on the Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and researchers entitled ''The Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application.'' This draft guidance provides information to those using radioactive drugs for certain research purposes to help determine whether research studies may be conducted under an FDA-approved radioactive drug research committee, or whether research studies must be conducted under an investigational new drug application (IND). It also offers answers to frequently asked questions on conducting research with radioactive drugs, and provides information on the membership, functions, and reporting requirements of a radioactive drug research committee approved by FDA.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by September 1, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Orhan Suleiman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2206, Silver Spring, MD 20993–0002, 301–796–1471.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and researchers entitled ''The Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application.''

On July 25, 1975 (40 FR 31298), FDA changed the conditions under which new radioactive drug and biological products could be used. The Agency terminated a 1963 order from the Commissioner of Food and Drugs (28 FR 183; January 8, 1963) that had exempted radioactive new drug and biological products for investigational use in humans from new drug requirements (part 312 (21 CFR part 312)), as long as they were shipped consistent with regulations issued by the Atomic Energy Commission (AEC). FDA and AEC had agreed that all radioactive drugs and biological products should now become subject to the same requirements for investigational use as other new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and section 351 of the Public Health Service Act (42 U.S.C. 262). Simultaneously, the agency issued regulations (§ 361.1 (21 CFR 361.1)) explaining when radioactive drugs for basic science and medical research would not be subject to the same requirements for investigational use as other new drugs.

Today, research studies with a radioactive drug or biological products may be conducted in a number of ways: (1) Under an IND (part 312), (2) exempt from IND requirements (§ 312.2), or (3) under certain conditions, with the supervision and approval of an FDA-approved Radioactive Drugs Research Committee (RDRC) (§ 361.1).

This guidance discusses the conditions under which research with a radioactive drug may be conducted under § 361.1. Appendices to the guidance answer frequently asked questions about those conditions and provide additional information on RDRCs. Appendix A of the draft guidance answers questions on basic science research with radioactive drugs. Appendix B addresses approval by the RDRC and the information that must be submitted by investigators to the RDRC. Appendix C discusses the limits on the pharmacological dose, and Appendix D discusses the limits on the radiation dose. Each of these appendices also includes a summary of the regulations. Appendix E provides information on the membership, functions, reports, and monitoring of an RDRC. The final appendix, Appendix F, is an RDRC review criteria checklist, indicating the areas on which the RDRC will focus when considering a proposed research study.

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 determining whether human research with a radioactive drug can be conducted under a radioactive drug research committee. 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 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 361.1 have been approved under OMB control number 0910–0053.

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 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: May 14, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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