

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D-0785]

**Guidances for Industry on Medical Imaging Drug and Biological Products;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three guidances for industry on “Developing Medical Imaging Drug and Biological Products.” These guidances are intended to assist developers of medical imaging drug and biological products (medical imaging agents) in planning and coordinating their clinical investigations and preparing and submitting investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and supplements to NDAs or BLAs.

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

ADDRESSES: Submit written requests for single copies of the guidances to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidances to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic

DDM Immediate Display
Display Date 6-17-04@12:54pm
Publication Date 6-22-04
Certifier J. Hawkins

comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidances.

FOR FURTHER INFORMATION CONTACT:

Sally Loewke, Center for Drug Evaluation and Research (HFD-160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7510, or

Kathleen Swisher, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a document announcing the availability of a draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologics." In a document published in the **Federal Register** of January 5, 1999 (64 FR 457), FDA reopened the comment period on the draft guidance until February 12, 1999. In a document published in the **Federal Register** of February 16, 1999 (64 FR 7561), FDA extended the comment period until April 14, 1999.

FDA received numerous written comments on the medical imaging draft guidance. In addition, the agency held public meetings on January 25 and March 26, 1999, to discuss various issues concerning the draft guidance. In the **Federal Register** of July 31, 2000 (65 FR 46674), the agency published a document announcing the availability of a revised draft guidance.

After considering the comments that FDA received on the revised draft guidance, the agency decided to revise the draft guidance, divide it into three parts to make it more user-friendly, and issue the three parts as drafts for

comment. In the **Federal Register** of May 19, 2003 (68 FR 27008), FDA published a document announcing the availability of the three parts.

Part 1 of “Medical Imaging Drug and Biological Products,” entitled “Conducting Safety Assessments,” provides recommendations on conducting safety assessments of medical imaging agents. Part 2, “Clinical Indications,” provides recommendations on tailoring clinical development programs for medical imaging agents to reflect the use of these agents for diagnosis and monitoring of diseases and conditions. Part 3, “Design, Analysis, and Interpretation of Clinical Studies,” provides recommendations on designing a clinical development program for a medical imaging agent, including selecting subjects, and on acquiring, analyzing, and interpreting medical imaging data. Collectively, these guidances provide information and recommendations on how to develop all types of medical imaging agents and how to comply with certain provisions in the final rule, published in the **Federal Register** of May 17, 1999 (64 FR 26657), on the evaluation and approval of in vivo radiopharmaceuticals used in diagnosis and monitoring. Having reviewed the comments that FDA received on each of the three parts, and having made appropriate changes, the agency is issuing final versions of these guidances.

These guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidances represent the agency’s current thinking on different aspects of the development of medical imaging agents. They do not create or confer any rights for or on any person and do 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 on the guidances at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the documents at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. The Paperwork Reduction Act of 1995

These guidances contain information collection provisions that 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 guidances would not impose any additional reporting burden because the submission of information on the safety and effectiveness of medical imaging agents in applications for marketing approval and INDs is already required by existing regulations. In fact, clarification by the guidances of FDA's standards for evaluation of medical imaging agents is expected to reduce the overall burden of information collection. FDA received no comments on the analysis of information collection burdens stated in the announcement of availability of the original draft guidance published in the **Federal Register** on October 14, 1998 (63 FR

55067). In the **Federal Register** of July 31, 2000 (65 FR 46674), the agency requested comments on the revised proposed collections of information. No comments were received.

Dated: 6/16/04

June 16, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

