

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0525]

Draft Guidance for Industry on New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.” As part of the Medical Device User Fee Amendments of 2007 (MDUFA) Commitment for the Performance Goals and Procedures, FDA agreed to publish draft guidance by September 30, 2008, for medical imaging devices with “contrast agents or radiopharmaceuticals.” FDA intends this draft guidance to assist developers of medical imaging devices and imaging drug/biological products that provide image contrast enhancement. Particularly this guidance focuses on approaches in developing new contrast indications for imaging devices for use with already approved imaging products. FDA intends for the recommendations in this guidance to promote timely and effective review of, and consistent and appropriate regulation and labeling for imaging drugs and devices.

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guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.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: Patricia Y. Love, Office of Combination Products (HFG–3), Office of the Commissioner, Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.” This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency’s current thinking on New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products. 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.

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 807 have been approved under 0910–0120. The collections of information in 21 CFR part 814 have been approved under 0910–0231. The collections of information in 21 CFR part 314 have been approved under 0910–0001.

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. 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: September 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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