Dated: December 12, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 99–141 Filed 1–4–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98D–0785]

Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of guidance; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 12, 1999, the comment period for the draft guidance for industry entitled ''Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics'' that appeared in the **Federal Register** of October 14, 1998 (63 FR 55067). FDA is taking this action in response to a request for an extension.

DATES: Written comments on the draft guidance may be submitted by February 12, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, FAX 888–CBERFAX or 301–827–3844. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Robert K. Leedham, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7510, or

George Q. Mills, Center for Biologics Evaluation and Research (HFM–573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–5097.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a notice announcing the availability of a draft guidance document for industry entitled ''Developing Medical Imaging Drugs and Biologics.'' The draft guidance is intended to assist developers of drug and biological products used for medical imaging, as well as radiopharmaceutical drugs used in disease diagnosis, in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The draft guidance also provides information on how the agency would interpret and apply provisions in proposed regulations, published in the **Federal Register** of May 22, 1998 (63 FR 28301), for in vivo radiopharmaceuticals used for diagnosis and monitoring. The draft guidance applies to medical imaging drugs that are used for diagnosis and monitoring and that are administered in vivo. The draft guidance is not intended to apply to possible therapeutic uses of these drugs or to in vitro diagnostic products. Interested persons were given until December 14, 1998, to submit written comments on the draft guidance.

FDA received a letter, dated December 4, 1998, from Alan M. Kirschenbaum, legal counsel for the Council on Radionuclides and Radiopharmaceuticals, requesting that the agency extend the comment period on the draft guidance by 60 days.

The draft guidance introduces several new and highly technical issues. Therefore, the agency has decided to reopen the comment period on the draft guidance until February 12, 1999, to allow the public more time to review and comment on its contents.

Interested persons may, on or before February 12, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any 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 draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–72 Filed 1–4–99; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 801

[REG 119192–98]

RIN 1545–AW80

Establishment of a Balanced Measurement System

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the adoption by the IRS of a balanced system to measure organizational performance within the IRS. These proposed regulations further implement a requirement that all employees be evaluated on whether they provided fair and equitable treatment to taxpayers and bar use of records of tax enforcement results to evaluate or to impose or suggest goals for any employee of the IRS. These regulations implement sections 1201 and 1204 of the Internal Revenue Restructuring and Reform Act of 1998. These regulations affect internal operations of the IRS and the systems that agency employs to evaluate the performance of organizations within IRS and individuals employed by IRS. This document also provides notice of public hearing on these proposed regulations.

DATES: Written comments and electronic comments must be received by March 8, 1999. Outlines of oral comments to be presented at the public hearing scheduled for Thursday, May 13, 1999 at 10 a.m. must be received by Thursday, April 22, 1999.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (REG–119192–98), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–119192–98), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option on