

(3) If it cannot be determined that the fasteners are correctly installed with wet sealant, remove and inspect the specified number of additional fasteners in that zone, oversize the holes, apply primer, and install new, oversize fasteners with wet sealant, in accordance with the alert service bulletin.

(i) If, after removal, all additional fasteners inspected in that zone are found to be correctly installed with wet sealant, no further action is required for that zone.

(ii) If, after removal, the fasteners in that zone are found to be incorrectly installed, remove all other fasteners in the zone, oversize the holes, apply primer, and install new, oversize fasteners with wet sealant, in accordance with the alert service bulletin.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on October 7, 1998.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 98-27481 Filed 10-13-98; 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. 98N-0040]

#### Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to November 16, 1998, the comment period on a proposed rule that was published in the **Federal Register** of May 22, 1998 (63 FR 28301). The document proposed to amend the drug and biologics regulations by adding

provisions that would clarify the evaluation and approval of in vivo radiopharmaceuticals used for diagnosis and monitoring. The agency is taking this action to provide interested persons additional time to submit comments to FDA on the proposed rule.

**DATES:** Written comments by November 16, 1998.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

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

Brian L. Pendleton, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5649.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 22, 1998 (63 FR 28301), FDA published a proposed rule to amend the drug and biologics regulations by adding provisions that would clarify the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The proposed regulations would describe certain types of indications for which FDA may approve diagnostic radiopharmaceuticals. The proposed rule would also include criteria that the agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. FDA provided until August 5, 1998, to submit comments on the proposed rule.

In the **Federal Register** of August 3, 1998 (63 FR 41219), FDA extended the comment period on the proposed rule until October 15, 1998, to allow interested persons additional time to submit comments on the proposed rule. FDA finds it appropriate to further extend the comment period to November 16, 1998, to permit interested persons the opportunity to consider the proposed rule in light of the agency's draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologics." Notice of the availability of this draft guidance is published elsewhere in this issue of the **Federal Register**.

Interested persons may, on or before November 16, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 2, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-27494 Filed 10-13-98; 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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Availability of guidance.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologics." This 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 will interpret and apply provisions in the proposed regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring, which published in the **Federal Register** of May 22, 1998 (63 FR 28301).

**DATES:** Written comments on the draft guidance may be submitted by December 14, 1998. 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