(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]

BILLING CODE 4910–13–U

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]

BILLING CODE 4160–01–F

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

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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Robert K. Leedham, Jr., Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 30857, 301–443–3500, 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:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance document entitled ''Developing Medical Imaging Drugs and Biologics.'' It references other CDER and CBER guidance documents that relate to the development of medical imaging drugs and biologics, including CBER's ''Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use'' (62 FR 9196, February 28, 1997). 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 applies to medical imaging drugs that are used for diagnosis and monitoring and that are administered in vivo. Such drugs include contrast agents used with medical imaging techniques such as radiography, computed tomography, ultrasonography, and magnetic resonance imaging, as well as radiopharmaceuticals used with imaging procedures, such as single-photon emission computed tomography and positron emission tomography. The draft guidance is not intended to apply to possible therapeutic uses of these drugs or to in vitro diagnostic products.

CDER's Division of Medical Imaging and Radiopharmaceutical Drug Products presented a preliminary version of this draft guidance document to the Medical Imaging Drug Advisory Committee (MIDAC) on October 26, 1996. Following that meeting, FDA worked with MIDAC to develop this draft guidance. As part of this process, FDA considered proposals submitted by an ad hoc group representing contrast agent manufacturers and by the Council on Radionuclides and Radiopharmaceuticals, Inc.

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). Section 122(a)(1) of the Modernization Act directs FDA to issue regulations on the approval of diagnostic radiopharmaceuticals. In the **Federal Register** of May 22, 1998 (63 FR 28301), FDA published a proposed rule on the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The proposed rule describes certain types of indications for which FDA would approve diagnostic radiopharmaceuticals and lists factors that the agency would consider in evaluating the safety and effectiveness of a diagnostic radiopharmaceutical under the Federal Food, Drug, and Cosmetic Act (the act) or the Public Health Service Act (the PHS Act). This draft guidance document provides information on how FDA intends to interpret and apply various sections of the proposed rule.

In the **Federal Register** of August 3, 1998 (63 FR 41219), FDA published a document extending the comment period on the proposed rule on in vivo radiopharmaceuticals from August 5, 1998, to October 15, 1998. In a separate document published elsewhere in this issue of the **Federal Register**, FDA is further extending the comment period to November 16, 1998. FDA hopes that the issuance of this draft guidance on medical imaging drugs and biologics, in conjunction with the extension of the comment period on the proposed rule, will assist interested persons in preparing their comments on the proposed rule. Persons will have additional time to submit comments on the draft guidance after the comment period on the proposed rule closes.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the development of medical imaging drugs and biologics. 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, regulations, or both.

II. Comments

Interested persons may, at any time, 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 should 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.

III. The Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is provided in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comment on the following: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics

Description: FDA is issuing a draft guidance on the development of 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 provides information on

how the agency will interpret and apply provisions of the existing regulations regarding the content and format of an application for approval of a new drug (21 CFR 314.50) and the content of a biological product application (21 CFR 601.25). In addition, the draft guidance provides information on how the agency will interpret and apply the proposed rule on the evaluation and approval of in vivo radiopharmaceuticals used for diagnosis and monitoring (63 FR 28301). The proposed rule, by adding part 315, would clarify existing FDA requirements for the evaluation and approval of drug and biological radiopharmaceuticals already in place under the authority of the act and the PHS Act.

Existing regulations, which appear primarily in parts 314 and 601 (21 CFR parts 314 and 601), specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of new drugs and biological products. This information is usually submitted as part of a new drug application (NDA) or a biologics license application (BLA), or as a supplement to an approved application. This draft guidance supplements these regulations. Under the proposed rule and the draft guidance, information required under the act and the PHS Act and needed by FDA to evaluate safety and effectiveness would still have to be reported.

Description of Respondents: Manufacturers of medical imaging drugs and biologics, including contrast drug products and diagnostic radiopharmaceuticals.

Burden Estimate: The proposed rule on in vivo radiopharmaceuticals used for diagnosis and monitoring sets forth an estimated annual reporting burden on the industry that would result from that rulemaking (63 FR 28301 at 28305 to 28306). This draft guidance on the development of medical imaging drugs and biologics is in part intended to explain how FDA will interpret and apply the proposed rule. Thus, the estimated annual reporting burden of the draft guidance, as provided in the chart below, is the same as that of the proposed rule, with one change. In addition to the diagnostic radiopharmaceuticals that are the subject of the proposed rule, the draft guidance also addresses the development of contrast drug products, which FDA evaluates and approves under part 314, but which are not affected by the proposed rule.

The chart below provides an estimate of the annual reporting burden for diagnostic radiopharmaceuticals and is based on the estimate described in the proposed rule (63 FR 28301 at 28306). The chart also provides an estimate for the annual reporting burden for contrast drug products. FDA estimates that the potential number of respondents who would submit applications or supplements for contrast drug products would be one. Although FDA did not approve any NDA's for contrast drugs (there are no biological contrast drug products) in fiscal year 1997 (FY 1997), for purposes of estimating the annual reporting burden, the agency assumes that it will approve one contrast drug each fiscal year. The annual frequency of responses for contrast drugs is estimated to be one response per application or supplement. The hours per response, which is the estimated number of hours that an applicant would spend preparing the information to be submitted for a contrast drug in accordance with this draft guidance, is estimated to be approximately 2,000 hours.

The draft guidance would not impose any additional reporting burden because safety and effectiveness information is already required by existing regulations. In fact, clarification by the draft guidance of FDA's standards for evaluation of medical imaging drugs and biologics is expected to reduce the overall burden of information collection. FDA invites comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	
Diagnostic Radiopharmaceuticals	8	1	8	2,000	16,000
Contrast Drugs	1	1	1	2,000	2,000
Total					18,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this draft guidance to OMB for review. Interested persons are requested to send comments on this information collection by November 13, 1998, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

IV. Electronic Access

An electronic version of this draft guidance document is available on the Internet using the World Wide Web (WWW) at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''.

Dated: October 6, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27495 Filed 10–13–98; 8:45 am]

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DEPARTMENT OF JUSTICE

Office of Juvenile Justice and Delinquency Prevention

28 CFR Part 31

[OJP (OJJDP)–1158]

RIN 1121–AA46

Juvenile Accountability Incentive Block Grants

AGENCY: Office of Juvenile Justice and Delinquency Prevention (OJJDP), Office of Justice Programs, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes procedures under which an eligible State, or unit of local government that receives a subgrant from the State, is