DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 94D–0422 and 93N–0005]

Revocation of Certain Guidance Documents on Positron Emission Tomography Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking two notices regarding guidance documents affecting positron emission tomography (PET) radiopharmaceutical drug products. The guidance documents address FDA's regulatory approach to PET drug products and current good manufacturing practice (CGMP) requirements for such products. FDA is revoking these notices along with the guidance documents to which the notices relate in accordance with provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the revocation of a final rule.

EFFECTIVE DATE: December 21, 1997.

FOR FURTHER INFORMATION CONTACT: 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: On November 21, 1997, President Clinton signed into law the Modernization Act (Pub. L. 105–115). Section 121(c)(1)(A) of the Modernization Act directs FDA to develop appropriate procedures for the approval of PET drugs as well as CGMP requirements for such drugs, taking into account any relevant differences between not-for-profit institutions that compound PET drugs and commercial manufacturers. FDA is to establish these procedures and requirements not later than 2 years after the date of enactment. In doing so, the agency must consult with patient advocacy groups, professional associations, manufacturers, and persons licensed to make or use PET drugs.

Under section 121(c)(2) of the Modernization Act, FDA cannot require the submission of new drug applications (NDA's) or abbreviated new drug applications (ANDA's) for compounded PET drugs that are not adulterated under section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) for a period of 4 years after the date of enactment, or 2 years after the date that the agency adopts special approval procedures and CGMP requirements for PET drugs, whichever is longer.

Section 121(d) of the Modernization Act requires FDA, within 30 days of enactment, to terminate the application of two notices that were published in the **Federal Register** on February 27, 1995 (60 FR 10593 and 10594). One notice is entitled ''Regulation of Positron Emission Tomography Radiopharmaceutical Drug Products; Guidance; Public Workshop'' (60 FR 10594). The notice included a guidance document entitled ''Regulation of PET Radiopharmaceuticals.'' This guidance document, among other things, stated that a manufacturer of a PET drug was required to obtain FDA approval of an NDA or ANDA in accordance with 21 CFR part 314.

In the other notice, FDA announced the availability of its ''Draft Guideline on the Manufacture of Positron Emission Tomography Radiopharmaceutical Drug Products'' (60 FR 10593). In the **Federal Register** of April 22, 1997 (62 FR 19580), FDA published a notice of availability of a final version of this guidance entitled ''Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products; Availability.'' The agency is hereby revoking these notices as well as the draft and final guidance documents on CGMP's for PET drugs.

Section 121(d) of the Modernization Act also directs FDA to terminate the application of a final rule, published in the **Federal Register** of April 22, 1997 (62 FR 19493), permitting the agency to approve requests from manufacturers of PET drug products for exceptions or alternatives to provisions of FDA's CGMP regulations (21 CFR 211.1(d)). FDA is announcing the revocation of this rule in a final rule published elsewhere in this issue of the **Federal Register**.

The notices and corresponding guidance documents discussed previously are revoked effective December 21, 1997.

In accordance with section 121(c)(1)(A) of the Modernization Act, FDA intends to begin the development of new PET drug approval procedures and CGMP requirements immediately and will obtain appropriate public input during this process.

Dated: December 16, 1997.

William B. Schultz,

Deputy Commissioner for Policy,

[FR Doc. 97–33188 Filed 12–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–3482–N–04]

Office of Lead Hazard Control; Notice of Proposed Information Collection: Comment Request

AGENCY: Office of Lead Hazard Control, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: February 17, 1998.

ADDRESSES: Interesed persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Ms. Ruth Wright, Reports Liaison Officer, Office of Lead Hazard Control (L), Department of Housing & Urban Development, 451—7th Street, SW, Room B–133, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: David Levitt at (202) 755–1785, extension 156 (this is not a toll-free number), Office of Lead Hazard Control, HUD, for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information: