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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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[Docket No. 99N-4063]

Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Preliminary Draft Proposed Rule; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of preliminary draft proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a preliminary draft proposed rule on current good manufacturing practice (CGMP) for positron emission tomography (PET) drug products. We are developing CGMP regulations for PET drug products in accordance with the Food and Drug Administration Modernization Act of 1997 (Modernization Act). We are making a preliminary draft of a proposed rule available to allow full discussion of its contents at an upcoming public meeting on CGMP requirements for PET drug products. We are announcing the availability of a companion draft guidance on CGMP for PET drug products elsewhere in this issue of the **Federal Register**.

DATES: A public meeting on the preliminary draft proposed rule and the draft guidance will be held on May 21, 2002. Submit written or electronic comments on the preliminary draft proposed rule by June 5, 2002.

ADDRESSES: A copy of the preliminary draft proposed rule will be on display at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the preliminary draft proposed rule to the Division of Drug Information (HFD-240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in

processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the preliminary draft proposed rule. Submit written comments to the Dockets Management Branch (address above). Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Brenda Uratani, Center for Drug Evaluation and Research (HFD-325), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-0098.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed the Modernization Act (Public Law 105-115) into law. Section 121(c)(1)(A) of the Modernization Act directs us to establish appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(1)(B) states that, in adopting such requirements, we must take due account of any relevant differences between not-for-profit institutions that compound PET drugs for their patients and commercial manufacturers of such drugs. Section 121(c)(1)(B) also directs us to consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists who make or use PET drugs as we develop PET drug CGMP requirements and approval procedures.

We presented our initial tentative approach to PET drug CGMP requirements and responded to numerous questions and comments about that approach at a public meeting on February 19, 1999. In the **Federal Register** of September 22, 1999 (64 FR 51274), we published a notice of availability of preliminary draft regulations on PET drug CGMP. Those preliminary draft regulations were discussed at a public meeting on September 28, 1999.

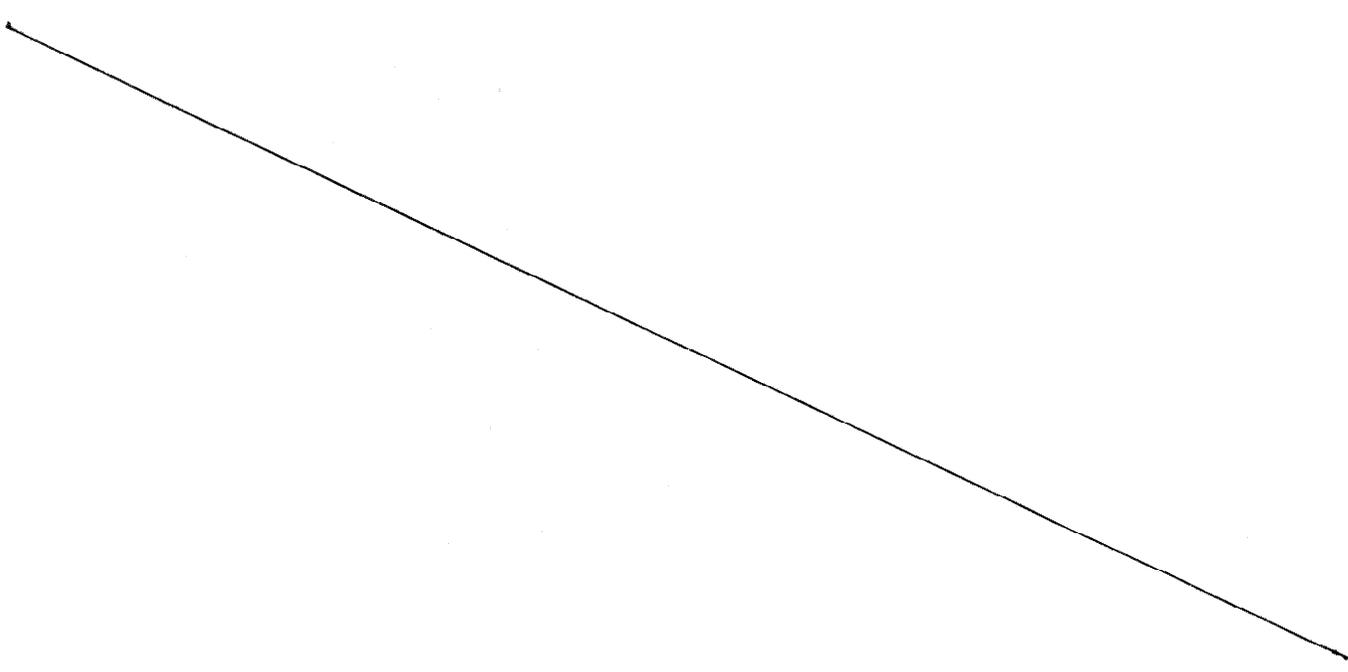
After considering the comments on the preliminary draft regulations, FDA has decided to make several revisions to its approach to CGMP for PET drug products. In accordance with 21 CFR 10.40(f)(4) and 10.80(b)(2), we are making revised preliminary draft regulations available for comment. The preliminary draft proposed rule does not include sections on the economic impact of the proposed rule, federalism concerns, and Paperwork Reduction Act issues. We will include

these sections when we publish a proposed rule, but we invite comments on these matters at this time.

Elsewhere in this issue of the **Federal Register**, we are announcing the availability of a companion draft guidance entitled "PET Drug Products—Current Good Manufacturing Practice (CGMP)." Both the preliminary draft proposed rule and the draft guidance will be discussed at a public meeting to be held on May 21, 2002, from 9 a.m. to 4:30 p.m., at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the preliminary draft 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. Electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. The preliminary draft proposed rule and the comments submitted to this docket may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm> or www.fda.gov/cder/fdama under "Section 121—PET (Positron Emission Tomography)."

(Authority: 21 U.S.C. 321 *et seq.*)

Dated: 12/26/01

December 26, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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