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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 212

[Docket No. 99N–4063]

Current Good Manufacturing Practices for Positron Emission Tomography Drug Products; Preliminary Draft Regulations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of preliminary draft regulations.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of preliminary draft regulations on current good manufacturing practices (CGMP's) for positron emission tomography (PET) drug products. FDA is developing CGMP's for PET drugs in accordance with the Food and Drug Administration Modernization Act of 1997 (Modernization Act). These preliminary draft regulations are being made available to allow full discussion of them at an upcoming public meeting on the regulation of PET drugs.

DATES: A public meeting on PET drug matters will be held on September 28, 1999. Submit written comments on or before October 13, 1999.

ADDRESSES: A copy of the preliminary draft regulations will be on display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the preliminary draft regulations may be obtained from the Drug Information Branch (HFD–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573, and the Center for Drug Evaluation and Research's Fax-on-Demand system at 301–827–0577 or 800–342–2722. An electronic version of the preliminary draft regulations is available on the Internet at ''http://www.fda.gov/cder/fdama'' under ''Section 121—

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PET (Positron Emission Tomography).'' Submit written comments to the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Tracy A. Roberts, Center for Drug Evaluation and Research (HFD–336), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0093.

SUPPLEMENTARY INFORMATION:

The President signed the Modernization Act (Public Law 105–115) into law on November 21, 1997. Section 121(c)(1)(A)(ii) of the Modernization Act directs FDA to establish within 2 years after enactment appropriate CGMP requirements for PET drugs.

Section 121(c)(1)(B) of the Modernization Act requires FDA to consult with patient advocacy groups, professional associations, manufacturers, and other interested persons as the agency develops PET drug CGMP requirements and approval procedures. To that end, the agency has conducted public meetings on PET drug matters and has established a public docket.

In accordance with section 121 of the Modernization Act, FDA has developed preliminary draft CGMP requirements for PET drug products. In accordance with 21 CFR 10.40(f)(4) and 10.80(b)(2), FDA has decided to make available to the public these preliminary draft CGMP regulations to facilitate discussion at the public meeting on PET drug matters to be held on September 28, 1999, from 9 a.m. to 4 p.m., at the Holiday Inn, Gaithersburg, MD (Goshen Room). Subsequently, FDA will issue a proposed rule on CGMP's for PET drug products and will invite comments on the proposed rule.

Interested persons may, on or before October 13, 1999, submit to the Dockets Management Branch (address above) written comments on the preliminary draft regulations. 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

preliminary draft regulations and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

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

Dated: 9/15/99
September 15, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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