

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0266]

0225 '02 MAR 11 P3:50

DMB
Display Date 3-12-02
Publication Date 3-13-02
Certifier G. LEDESMA

Draft Guidance on Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "PET Drug Products—Current Good Manufacturing Practice (CGMP)." We are announcing the availability of preliminary draft proposed regulations elsewhere in this issue of the **Federal Register**. We are making the draft guidance available so that producers of positron emission tomography (PET) drugs will better understand FDA's thinking concerning CGMP compliance if the preliminary draft proposed regulations were to become final after notice and comment rulemaking.

DATES: A public meeting on the preliminary draft proposed regulations and the draft guidance will be held on May 21, 2002.

Submit written or electronic comments on the draft guidance by June 5, 2002.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 Food and Drug Administration Modernization Act of 1997 (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 the 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.

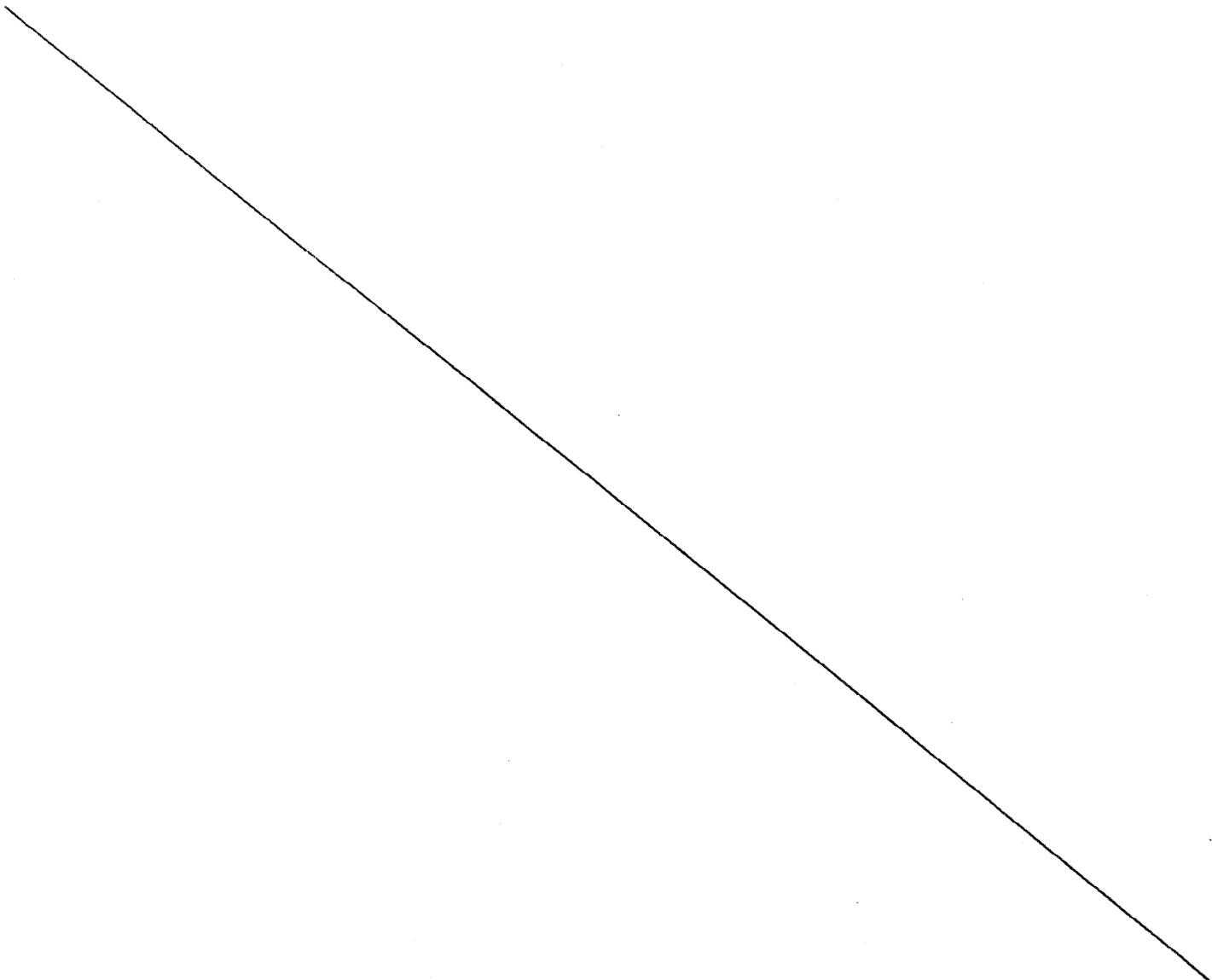
We presented our initial tentative approach to PET drug CGMP requirements and responded to numerous questions and comments about that approach at a public meeting on February 19, 1999. In the **Federal Register** of September 22, 1999 (64 FR 51274), we published a notice of availability of preliminary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

After considering the comments on the preliminary draft regulations, we have decided to make several revisions to those regulations. Elsewhere in this issue of the **Federal Register**, we are announcing the availability of a preliminary draft proposed rule on CGMP for PET drug products. We are making this draft guidance available now so that PET drug producers will better understand FDA's thinking concerning compliance with the preliminary draft proposed CGMP regulations if they were to become final after notice and comment rulemaking. We invite comments on whether the guidance would be a useful accompaniment to the proposed rule. 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 draft guidance. 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 draft guidance and the comments submitted to the docket may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

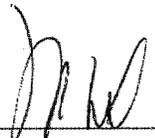


III. Electronic Access

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

Dated: 12/26/01

December 26, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-⁷???? Filed ??-??-01⁷; 8:45 am]

BILLING CODE 4160-01-S^{2/1}

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