

JMB

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0892]

Draft Guidance for Industry on the Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products;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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "PET Drug Applications —Content and Format for NDA's and ANDA's." The draft guidance is intended to assist manufacturers of certain positron emission tomography (PET) drugs in submitting new drug applications (NDA's) or abbreviated new drug applications (ANDA's) in accordance with a notice entitled "Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications" published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on the draft guidance and the collection of information provisions by *[insert date 90 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> and at <http://www.fda.gov/cder/regulatory/pet>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug

NAD-1

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.

FOR FURTHER INFORMATION CONTACT: Robert K. Leedham, Jr., Center for Drug Evaluation and Research (HFD-160), 5600 Fishers Lane, Rockville, MD 20857, 301-827-7510.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "PET Drug Applications—Content and Format for NDA's and ANDA's." The draft guidance is intended to assist the manufacturers of certain PET drugs—fludeoxyglucose (FDG) F 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection—in submitting NDA's and ANDA's in accordance with a notice entitled "Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications" published elsewhere in this issue of the **Federal Register**. The notice invites the manufacturers of these PET drugs to submit NDA's of the type described in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(2)) or ANDA's under section 505(j) of the act. The draft guidance states when submission of a 505(b)(2) application or ANDA is appropriate, and it describes the information that manufacturers of these PET drugs should include in each type of application.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the submission of 505(b)(2) applications and ANDA's in accordance with a notice published elsewhere in this issue of the **Federal Register**. 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.

Interested persons may submit to the Dockets Management Branch (address above) written 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. The draft guidance and received comments are

available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on: (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: PET Drug Applications—Content and Format for NDA’s and ANDA’s.

Description: The draft guidance is intended to assist manufacturers of certain PET drugs in submitting NDA’s or ANDA’s in accordance with the notice entitled “Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications.”

Description of Respondents: Manufacturers submitting NDA's or ANDA's for certain PET drugs.

Burden Estimate: The draft guidance is intended to assist manufacturers in preparing NDA's or ANDA's for FDG F 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection submitted in accordance with a notice entitled "Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications" published elsewhere in this issue of the **Federal Register**. Most of the collection of information resulting from this draft guidance is contained in current regulations for submitting NDA's and ANDA's to FDA under part 314 (21 CFR part 314), and has already been reviewed and approved by OMB as follows: (1) Information collection required under part 314 is approved by OMB until November 30, 2001, under OMB control number 0910-0001; (2) information collection required on Form FDA-356h (Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use) is approved by OMB until April 30, 2000, under OMB control number 0910-0338; and (3) information collection required on Form FDA-3397 (User Fee Cover Sheet) is approved by OMB until April 30, 2001, under OMB control number 0910-0297.

There are three types of submissions requested under the draft guidance that are not specifically required under part 314 or Form FDA-356h or Form FDA-3397 and, therefore, need to be approved by OMB under the PRA:

1. Cover letter—Manufacturers should include with each NDA or ANDA a signed and dated cover letter with a clear, brief introductory statement. The draft guidance specifies the information that should be contained in the cover letter: (1) Purpose of the application; (2) type of submission; (3) name, title, signature, and address of the applicant; (4) established name and proprietary name for the proposed drug product; and (5) number of volumes submitted.

2. Letter of authorization—Manufacturers using an agent or consultant to act on their behalf should include with each NDA or ANDA a letter of authorization, signed and attached to the cover letter, that identifies the authorized agent or consultant.

3. Sample statement—Manufacturers should include a sample statement when responding to an FDA request for a representative sample of the drug product proposed for marketing, the drug substance or components used in the manufacture of the drug product, or the reference standards. The draft guidance provides an example of a sample statement notifying FDA that the applicant is supplying a representative sample of the drug product, the drug substance or components, or the reference standards.

Based on FDA's experience with reviewing NDA's and ANDA's and on its knowledge of the PET drug manufacturing community, FDA has estimated, in table 1 of this document: (1) The number of respondents expected to submit cover letters, letters of authorization, and sample statements with their NDA's or ANDA's as set forth in the draft guidance; (2) the number of cover letters, letters of authorization, and sample statements that respondents will submit with their NDA's or ANDA's as set forth in the draft guidance; and (3) the amount of time it will take respondents to submit cover letters, letters of authorization, and sample statements with their NDA's or ANDA's as set forth in the draft guidance.

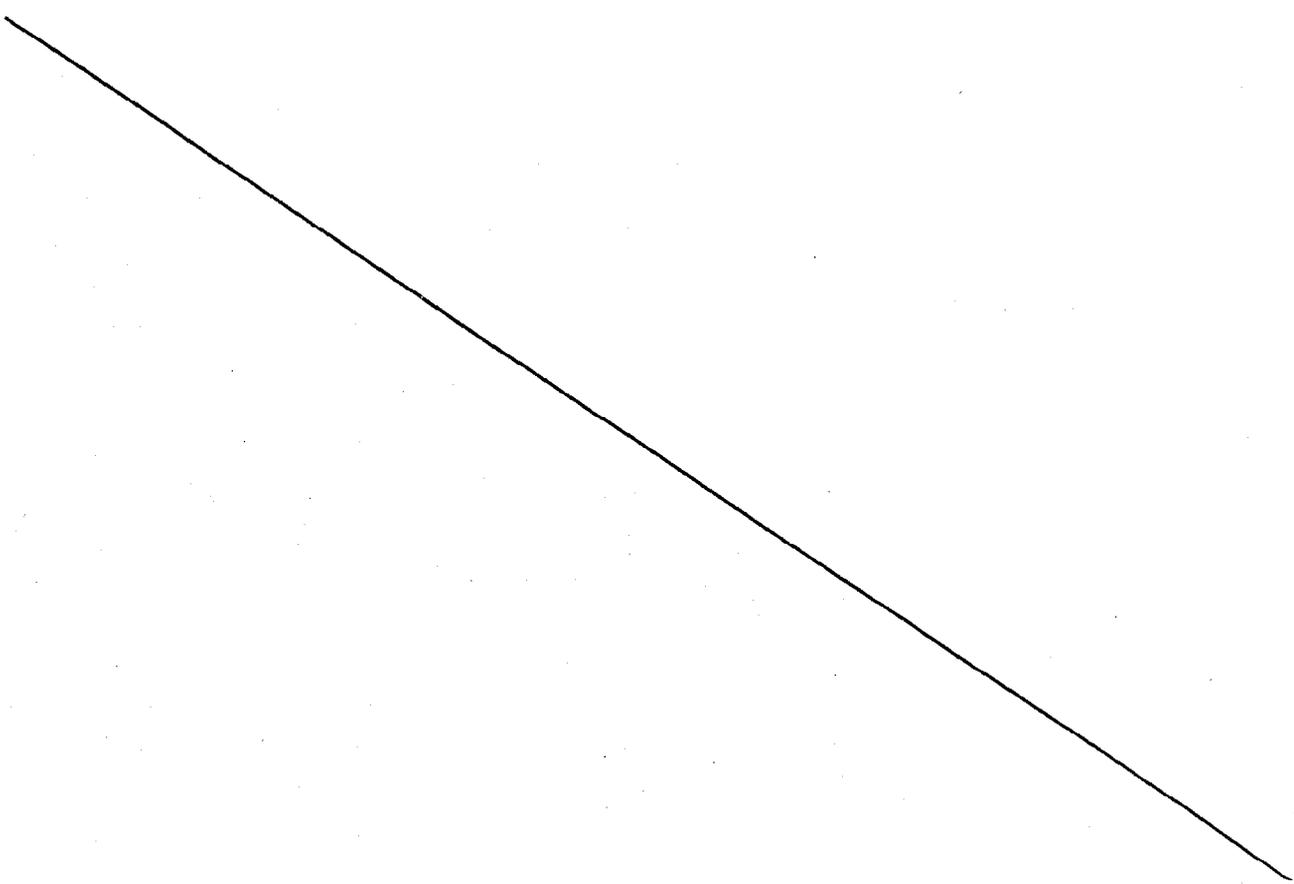
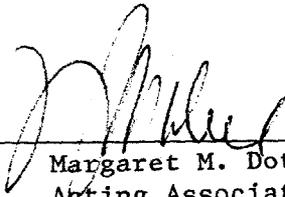


TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

NDA's and ANDA's	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Cover letters	50	1	50	1/2	25
Letters of authorization	20	1	20	1/2	10
Sample statements	1	1	1	1/2	.5
Total					35.5

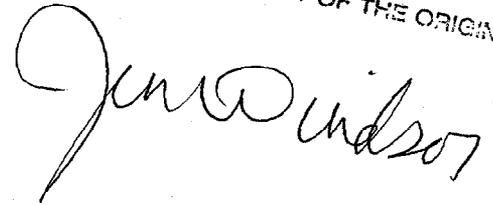
¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 3/6/00
March 6, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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