

were effective January 1, 2012. Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each state in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary.

Based upon HHS' experience in the MLR data collection and evaluation process, HHS is updating its annual burden hour estimates to reflect the actual numbers of submissions, rebates and rebate notices. In addition, the notice requirement for issuers that do not owe rebates applied only to the 2011 reporting year, and does not apply to 2012 and subsequent MLR reporting years.

We have simplified the format of the reporting form and the method by which issuers submit their data. For the 2012 MLR reporting year, when submitting data to CMS, issuers will have the option to use either a Microsoft Excel (.xls) or a Comma Separated Value (.csv) file format. This will allow issuers flexibility and reduce the burden in submitting the MLR report. The new method will no longer include pre-calculated fields which will reduce the burden as well as the possibility of error.

The 2012 MLR Reporting Form and instructions also reflect changes for the 2012 reporting year and beyond that are set forth in the December 2011 Final Rule as to whether certain already reported expenditures such as ICD-10 conversion costs are taken into account in calculating an issuer's MLR.

HHS has created and published a host of electronic training tools to assist issuers with the preparation and submission of MLR data forms and Rebate calculations. Consequently the agency is reducing its current burden hours from 354,570 to 311,302. *Form Number:* CMS-10418 (OCN: 0938-1164); *Frequency:* Annual submission for each respondent; *Affected Public:* Private Sector, Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 502; *Number of Responses:* 3,085; *Total Annual Hours:* 311,302. (For policy questions regarding this collection, contact Carol Jimenez at (301) 492-4457. For all other issues, call (410) 786-1326.)

To obtain copies of the supporting statement and any related forms for the

proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by February 4, 2013:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 29, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012-29243 Filed 12-3-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0081]

Guidance on Investigational New Drug Applications for Positron Emission Tomography Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs." The guidance is intended to assist manufacturers of PET drugs in submitting investigational new drug applications (INDs).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Kyong (Kaye) Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2352, Silver Spring, MD 20993-0002, 301-796-2050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs." The guidance summarizes the IND process for PET drugs, makes recommendations for how to submit an IND, provides advice on expanded access options for investigational PET drugs, and describes the process for requesting permission to charge for an investigational PET drug.

A draft guidance of the same title was announced in the **Federal Register** on February 14, 2012 (77 FR 8262), and Docket No. FDA-2012-D-0081 was open for comments until May 14, 2012. We received comments from industry and professional societies. We have carefully considered, and where appropriate, we have made corrections, added information, or clarified the information in this guidance in response to the comments or on our own initiative.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the submission of INDs for PET drugs. 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 and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). INDs and requests to charge for a drug under an IND are submitted to FDA under part 312 (21 CFR part 312). New drug applications and abbreviated new drug applications are submitted to FDA under §§ 314.50 and 314.94 (21 CFR 314.50 and 314.94). The collections of information in part 312 and in §§ 314.50 and 314.94 have been approved under OMB control numbers 0910–0014 and 0910–0001.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29163 Filed 12–3–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0080]

Guidance on Food and Drug Administration Oversight of Positron Emission Tomography Drug Products—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of a guidance entitled “FDA Oversight of PET Drug Products—Questions and Answers.” This guidance provides questions and answers that address nearly all aspects of the FDA approval and surveillance processes, including application submission, review, compliance with good manufacturing practices, inspections, registration and listing, and user fees.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6164, Silver Spring, MD 20993–0002, 301–796–3416.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled “FDA Oversight of PET Drug Products—Questions and Answers.” In 1997, Congress passed the Food and Drug Administration Modernization Act (the Modernization Act) (Public Law 105–115). Section 121 of the Modernization Act directed FDA to establish appropriate approval procedures and current good manufacturing practices (CGMP) for PET drugs. The procedures were finalized and an implementation timeline was instituted on December 10, 2009, when FDA published regulations that described the minimum CGMP standards that each PET drug manufacturer is to follow during the production of a PET drug (see part 212 (21 CFR part 212)).¹ Under the requirements of section 121 of the Modernization Act, within 2 years

¹ The regulation, CGMP guidance, and supportive information, including historical documents, are available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm085783.htm>.

following that publication date, a new drug application (NDA) or abbreviated new drug application (ANDA) must be submitted for any PET drug marketed for clinical use in the United States.

Recognizing that many PET drug producers are unfamiliar with the drug approval process, FDA issued several guidance documents specific to PET drug producers² and held a public meeting in March 2011 to assist applicants in preparing NDAs and ANDAs for the three most commonly used PET drugs. Numerous questions have been raised since that public meeting on all aspects of FDA oversight of PET drugs. This guidance is being issued to respond to the questions that have been submitted to date, and it will be revised periodically to respond to additional questions that have been submitted and are expected to be submitted in the future.

A draft guidance of the same title was announced in the **Federal Register** on February 27, 2012 (77 FR 11553), and Docket No. FDA 2012–D–0080 was open for public comment until May 29, 2012. We received one set of comments from industry. We have carefully considered the comments, and where appropriate, we have made corrections, added information, or clarified the information in this guidance in response to the comments or on our own initiative. In addition, we have added six new questions and answers (see questions 63, 64, 65, 66, 88, and 89).

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on the FDA oversight of PET drugs. 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 and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m.

² We update guidances periodically. To make sure you have the most recent version of a guidance, check FDA’s Drugs guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.