

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]

BILLING CODE 4160–01–P

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

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

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¹ The regulation, CGMP guidance, and supportive information, including historical documents, are available at 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

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>.

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). The collections of information in 21 CFR part 314 were approved under OMB control numbers 0910–0001 and 0910–0338; the collections of information in 21 CFR part 312 were approved under OMB control number 0910–0014; the collections of information in part 212 were approved under OMB control number 0910–0667; the collections of information in 21 CFR parts 210 and 211 were approved under 0910–0139; and the collections of information in 21 CFR part 207 were approved under OMB control number 0910–0045. The guidance also refers to collections of information associated with submitting Form FDA 3397 (Prescription Drug User Fee Cover Sheet), approved under OMB control number 0910–0297.

IV. Electronic Access

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

Dated: November 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29157 Filed 12–3–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1040]

Antiseptic Patient Preoperative Skin Preparation Products; Public Hearing; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of November 21, 2012 (77 FR 69863). The document announced a public hearing entitled “Antiseptic Patient Preoperative Skin Preparation

Products.” The document was published with an incorrect email address. This document corrects that error. Due to this error, FDA is extending the *Requests for Oral Presentations* registration date from November 27, 2012, to December 7, 2012.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Silver Spring, MD 20903, 301–796–3441, Fax: 301–847–8753, email: CDER-AntisepticPreOpPublicMeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 21, 2012, in FR Doc. 2012–28357, on page 69863, the following corrections are made:

1. On page 69863, in the second column, under *Contact Person*, the email address “*AntisepticPreOpPublicMeeting@fda.hhs.gov*” is corrected to read “*CDER-AntisepticPreOpPublicMeeting@fda.hhs.gov*”.

2. On page 69863, in the third column, under *Requests for Oral Presentations*, the date “November 27, 2012” is changed to read “December 7, 2012.”

Dated: November 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29166 Filed 12–3–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Device Good Manufacturing Practice Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organization interested in participating in the selection of nonvoting industry representatives to serve on the Device Good Manufacturing Practice Advisory

Committee (DGMPAC) in the Center for Devices and Radiological Health notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organizations interested in participating in the selection of an appropriate nonvoting members to represent industry interests must send a letter stating that interest to FDA by January 3, 2013, for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by January 3, 2013.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Margaret J. Ames (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Margaret J. Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5234, Silver Spring, MD 20993, 301–796–5960, margaret.ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 520 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j), as amended, provides that the DGMPAC shall be composed of two representatives of interests of the device manufacturing industry. The Agency is requesting nominations for nonvoting industry representatives on the DGMPAC.

I. Function of DGMPAC

Review proposed regulations issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

II. Qualifications

Persons nominated for the DGMPAC should possess appropriate qualifications to understand and contribute to the committee’s work as described in the committee’s function.