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 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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.


Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2012–29157 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–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.


SUPPLEMENTARY INFORMATION:

Correction

In the Federal Register of November 21, 2012, in FR Doc. 2012–28337, 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 69663, in the third column, under Requests for Oral Presentations, the date “November 27, 2012” is changed to read “December 7, 2012.


Leslie Kux,
Assistant Commissioner for Policy.

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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 20903, 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.