

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](mailto: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](mailto: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.

### III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within the 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

### IV. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from device manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: November 28, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-29165 Filed 12-3-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project: Substance Abuse Prevention and Treatment Block Grant Synar Report Format, FFY 2014-2016—(OMB No. 0930-0222)—Revision

Section 1926 of the Public Health Service Act [42 U.S.C. 300x-26] stipulates that funding Substance Abuse Prevention and Treatment Block Grant (SABG) agreements for alcohol and drug abuse programs for fiscal year 1994 and subsequent fiscal years require states to have in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18. This section further requires that states conduct annual, random, unannounced inspections to ensure compliance with the law; that the state submit annually a report describing the results of the

inspections, the activities carried out by the state to enforce the required law, the success the state has achieved in reducing the availability of tobacco products to individuals under the age of 18, and the strategies to be utilized by the state for enforcing such law during the fiscal year for which the grant is sought.

Before making an award to a State under the SABG, the Secretary must make a determination that the state has maintained compliance with these requirements. If a determination is made that the state is not in compliance, penalties shall be applied. Penalties ranged from 10 percent of the Block Grant in applicable year 1 (FFY 1997 SABG Applications) to 40 percent in applicable year 4 (FFY 2000 SABG Applications) and subsequent years. Respondents include the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands.

Regulations that implement this legislation are at 45 CFR 96.130, are approved by OMB under control number 0930-0163, and require that each state submit an annual Synar report to the Secretary describing their progress in complying with section 1926 of the PHS Act. The Synar report, due December 31 following the fiscal year for which the state is reporting, describes the results of the inspections and the activities carried out by the state to enforce the required law; the success the state has achieved in reducing the availability of tobacco products to individuals under the age of 18; and the strategies to be utilized by the state for enforcing such law during the fiscal year for which the grant is sought. SAMHSA's Center for Substance Abuse Prevention will request OMB approval of revisions to the current report format associated with Section 1926 (42 U.S.C. 300x-26). The report format is not changing significantly. Any changes in either formatting or content are being made to simplify the reporting process for the states and to clarify the information as the states report it; both outcomes will facilitate consistent, credible, and efficient monitoring of Synar compliance across the states. All of the information required in the new report format is already being collected by the states. Specific changes are listed below:

#### Clarification Changes

To decrease the need for supplemental questions and reporting,