effectiveness of the device. Therefore, the relevant question is whether a device should be classified as class I and be subject only to general controls, or whether class II controls are necessary to provide reasonable assurance of the safety and effectiveness of the device. On the basis of information described previously concerning the risks associated with the fiber optic light sources, FDA believes that this device is appropriately in class II.

The petitioner presented no new information, in the form of valid scientific evidence, on which FDA could rely to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device for its intended use. FDA, therefore, is denying the petition.

VI. Reference

The following information has been placed on display in the Dockets Managements Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting Search Information, 5 pp.

Dated: September 9, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–28563 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 22, 1999, 8 a.m. to 5 p.m. and November 23, 1999, 7:45 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8210 Wisconsin Ave., Bethesda, MD.

Contact Person: Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12545. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 22, 1999, FDA will discuss its regulations related to ozone-depleting substances. In this discussion, FDA will review the Montreal Protocol on substances that deplete the ozone layer and the advanced notice of proposed rulemaking published on March 6, 1997 (62 FR 10242), as discussed at the April 11, 1997, committee meeting. FDA will provide an overview and detailed discussion of the proposed rule published on September 1, 1999 (64 FR 47719), related to the phase-out of chlorofluorocarbons (CFC's) in metered-dose inhalers. The proposed rule outlines the mechanism by which FDA will determine when the use of ozone-depleting substances, including CFC's in metered-dose, inhalers, in any product regulated by FDA is no longer essential under the Clear Air Act. The proposed rule can be downloaded at http://www.fda.gov/ohrma/dockets/98fr/090199b.pdf. FDA has also created a website at http://www.fda.gov/cder/mdi to provide information to the public regarding this proposal and the issues related to CFC use in medical products. The committee will discuss and comment on the proposed rule and on the presentations made during the public hearing.

On November 23, 1999, the committee will discuss the safety and efficacy of new drug application (NDA) 21–077 for three products: (1) Advair™ Diskus® 100 micrograms (µg) (salmeterol xinafoate 50 µg/fluticasone propionate 100 µg inhalation powder), (2) Advair™ Diskus® 250 µg (salmeterol xinafoate 50 µg/fluticasone inhalation powder), and (3) Advair™ Diskus® 500 µg (salmeterol xinafoate 50 µg/fluticasone propionate 500 µg inhalation powder), Glaxo Wellcome, for the maintenance treatment of asthma as prophylatic therapy in patients 12 years of age and older.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 12, 1999. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12:30 p.m. on November 22, 1999, and between approximately 8 a.m. and 8:30 a.m. on November 23, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 22, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–28559 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4491]

FDA's Proposed Strategy on Reuse of Single Use Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''FDA's Proposed Strategy on Reuse of Single-Use Devices.'' The document presents the agency's current thinking about the best way to address the concerns regarding the practice of reprocessing and reusing devices that are labeled, or otherwise intended, for one use only (referred to as ''single use devices'' (SUD's)). The strategy outlined in the document is based, in part, on information and suggestions the agency received during the May 5 and 6, 1999, conference on Reuse of Single-Use Devices, which the agency cosponsored with the Association for the Advancement of Medical Instrumentation (AAMI). The document reflects FDA's belief that the optimum approach to this issue will involve action by the agency and all of the affected stakeholders. The agency is soliciting comments, proposals for alternative approaches, and information on this issue. In a future issue of the **Federal Register**, the agency will announce an open meeting, to be held

in Rockville, Maryland on December 14, 1999, to gather comments on the agency's proposed strategy.

DATES: Submit written comments at anytime.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the document. Submit written requests for single copies (on a 3.5″ diskette) of ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Larry D. Spears, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4646.

SUPPLEMENTARY INFORMATION:

I. Background

Reuse of SUD's is the practice of cleaning, disinfecting, sterilizing, and reusing medical devices that are intended for only one use. Reuse has raised concerns regarding patient safety, informed consent, and equitable regulation of reuse under the Federal Food, Drug, and Cosmetic Act. On May 5 and 6, 1999, FDA and AAMI cosponsored a conference on Reuse of Single-Use Devices to help examine policy alternatives regarding the practice of reuse. At that time, the agency committed to publishing a response to the positions expressed at the conference in the **Federal Register** by no later than October 1999. ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' is that response.

II. Significance of the Proposed Strategy Document

''FDA's Proposed Strategy on Reuse of Single-Use Devices'' represents options that the agency is considering on the reuse of single-use devices.

III. Electronic Access

In order to receive ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 2525 followed by the pound sign (). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''FDA's Proposed Strategy on Reuse of Single-Use Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this document. Submit two copies of any comments, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The agency will consider such comments when determining their final strategy. ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' and any received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28807 Filed 11–1–99; 12:19 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4114]

Draft ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors.'' The draft guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. When finalized, the draft guidance document is intended to supplement the guidance document entitled ''Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy,'' dated March 1998, and a letter to Sponsors of an IND Using Retroviral Vectors, dated September 20, 1993.

DATES: Written comments may be submitted at any time, however, comments should be submitted by February 1, 2000, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–