Requests to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter. Depending on the time available and the number of requests to make oral comments, it may be necessary to limit the time of each presenter.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Anne Wilson, Program Analyst, Office of the Director, NCEH, CDC, 4770 Buford Highway, NE, M/S F49, Atlanta, Georgia 30341–3724, telephone 770/488–7321, e-mail amw6@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 30, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–29601 Filed 11–4–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Antiviral Drugs Advisory Committee and the Nonprescription 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: Antiviral Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee.

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

Date and Time: The meeting will be held on December 1, 1998, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Rhonda W. Stover or Sandra L. Titus, 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 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will jointly discuss new drug application (NDA) N20–629, to switch penciclovir (Denavir®, SmithKline Beecham) topical cream from prescription status to over-the-counter status for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

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 24, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 24, 1998, 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 27, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–29561 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0298]

Guidance for Industry on General/ Specific Intended Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry on General/ Specific Intended Use.'' FDA developed this guidance to satisfy a new section of the Federal Food, Drug, and Cosmetic Act (the act), which was added by the Food and Drug Administration Modernization Act of 1997 (FDAMA). This new section directs the agency to issue guidance explaining the general principles used by FDA in determining when a specific use may be added to a legally marketed device using premarket notification (510(k)) procedures and when a specific use triggers the need for a premarket approval (PMA) application.

DATES: Written comments concerning this guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your electronic or written request, or fax your request to 301–443–8818. Submit written comments on ''Guidance for Industry on General/Specific Intended Use'' to the contact person. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance entitled ''Guidance for Industry on General/Specific Intended Use.''

FOR FURTHER INFORMATION CONTACT: Daniel G. Schultz, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–5072.

SUPPLEMENTARY INFORMATION:

I. Background

Congress indicated that FDA should provide additional guidance on the approach that the agency takes when evaluating whether a new use, which appears to fall within the scope of the intended use of a legally marketed predicate device, is a new intended use that would require a PMA. This guidance is issued in accordance with the new section 513(i)(1)(F) of the act (21 U.S.C. 360c(i)(1)(f)), which was added by section 206 of FDAMA. The purpose of this document is to help medical device manufacturers understand the principles used by FDA to determine whether the addition of a specific indication for use to a medical device cleared for marketing with a general indication for use could trigger the need for a PMA application. The guidance is intended to help manufacturers answer the following questions: Under what circumstances is the device with a new, specific indication for use likely to be found to be substantially equivalent to a device legally marketed for a general indications for use? Conversely, when does a specific indication for use become a new intended use that requires submission of a PMA to establish the safety and effectiveness of the device? FDA announced the

availability of a draft guidance pertaining to General/Specific Intended use in the **Federal Register** of May 22, 1998 (63 FR 28392). The agency received two comments on the draft guidance. FDA has reviewed the comments and has made some revisions to the guidance in response to the comments.

II. Significance of Guidance

This guidance document represents the agency's current thinking on General/Specific Intended Use. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance for Industry on General/Specific Intended Use'' via your fax machine, call the CDRH Facts-On-Demand (FOD) 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 second voice prompt press 2, and then enter the document number 499 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Guidance for Industry on General/Specific Intended Use,'' 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 written comments regarding this final guidance to the contact person. Such comments will be considered when determining whether to amend the current guidance.

Dated: October 28, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29567 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0729]

Draft ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors.'' This draft guidance is not final nor is it in effect at this time. FDA recognizes the importance of providing applicants and other interested parties the agency's 510(k) submission criteria for washers and washer-disinfectors intended to process reusable medical devices. The intent of this draft guidance is to provide specific directions regarding information and data which should be submitted to FDA in 510(k) submission for these types of devices. This draft guidance is posted on the Internet and will be included in the panel package for the formal classification of these devices at the General Hospital and Personal Use Devices Panel meeting on September 14, 1998.

DATES: Written comments concerning this guidance must be received by February 3, 1999.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' 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. Written comments concerning this guidance must be submitted 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. Submit written comments on ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' to the contact person listed below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

Washers and washer-disinfectors intended for cleaning and disinfection of reusable medical devices, such as stainless steel devices, surgical instruments, including devices with lumens, respiratory therapy equipment, and other medical devices, were legally marketed devices prior to the enactment of the Medical Device Amendments of 1976. These devices are considered ''unclassified'' medical devices. On June 2, 1998, FDA published on the Internet a guidance document entitled ''CDRH Guidance Document for Washers and Washer–Disinfectors Intended for Processing Reusable Medical Devices'' to provide direction to the regulated industry on when a premarket notification [510(k)] submission is required for these unclassified washers and washer-disinfectors. In the ''CDRH Guidance Document for Washers and Washer–Disinfectors Intended for Processing Reusable Medical Devices,'' the agency made the commitment to provide industry with guidance on the information and data which should be included in a 510(k) submission. This draft guidance entitled ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' provides regulated industry with specific guidance on the information and data that should be included in a 510(k) submission for these devices.

These unclassified washers and washer-disinfectors will undergo formal classification at the September 14, 1998, General Hospital and Personal Use Devices Panel meeting.

II. Significance of Guidance

This draft guidance represents the agency's current thinking on the