The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority of 21 CFR 5.82, finds that the holders of the applications listed above have repeatedly failed to submit reports required by § 314.81. Therefore, under this finding, approval of the applications listed above, and all amendments and supplements thereto, is hereby withdrawn, effective February 2, 2001.

Dated: January 9, 2001.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 01–2790 Filed 2–1–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral 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.

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

Date and Time: The meeting will be held on February 27, 2001, 9 a.m. to 5:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: TurnerT@cder.fda.gov, 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 committee will discuss new drug application (NDA) 21–304, valganciclovir hydrochloride tablets, 450mg, Syntex (U.S.A.) LLC, proposed for treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome (AIDS).

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 February 20, 2001. 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 February 20, 2001, 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: January 18, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–2788 Filed 2–1–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0027]

Guidance for Industry on Statistical Approaches to Establishing Bioequivalence; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Statistical Approaches to Establishing Bioequivalence.'' This guidance provides recommendations to sponsors and/or applicants who intend to use equivalence criteria in analyzing in vivo or in vitro bioequivalence (BE) studies for investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's) and supplements to these applications. The guidance discusses the use of average, population, and individual BE approaches to compare in vivo and in vitro bioavailability (BA) measures. (This guidance replaces the draft guidance that was issued in 1999 entitled ''Average, Population, and Individual Approaches to Establishing Bioequivalence.'')

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mei-Ling Chen, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5688.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Statistical Approaches to Establishing Bioequivalence.'' This guidance provides information on statistical approaches for sponsors and/or applicants intending to provide BA and BE information to the agency in IND's, NDA's, ANDA's, and their supplements.

Over the years, BA/BE data have been analyzed using an average BE approach. This statistical guidance describes two new approaches for analysis, population and individual BE. This guidance does not provide information about when an approach should be used; that information is provided in other FDA BA/BE guidances. Instead, the guidance provides recommendations on how to use each of these approaches once one has been selected.

This guidance is a final revision of a document that began with the publication of a preliminary draft guidance on this subject entitled ''In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches'' in 1997 (62 FR 67880, December 30, 1997), and was followed by a draft guidance entitled ''Average, Population, and Individual Approaches to Establishing Bioequivalence,'' published in 1999 (64 FR 48842, September 8, 1999). This final guidance replaces both of these draft guidances and a 1992 FDA guidance entitled ''Statistical Procedure for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design.''

In September 1999, FDA announced the availability of a draft guidance entitled ''BA and BE Studies for Orally Administered Drug Products—General Considerations'' (64 FR 48409, September 3, 1999). That draft guidance was intended to provide general information on how to comply with the BA and BE requirements in part 320 (21 CFR part 320) for orally administered dosage forms. When that draft guidance was published, FDA received a total of 16 public comments, a number of which