

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under this finding, approval of the applications listed above, and all amendments and supplements thereto, is hereby withdrawn, effective February 2, 2001.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]

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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]

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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

expressed concern about the use of the individual BE approach.

FDA acknowledged the public concerns about the use of the individual BE approach when the final guidance entitled "BA and BE Studies for Orally Administered Drug Products—General Considerations" (65 FR 64449, October 27, 2000) was issued. In that guidance, FDA recommends the continued use of the average BE approach for both replicated and nonreplicated studies. However, that guidance states that sponsors have the option to choose another approach, e.g., an individual BE approach for highly variable drugs. The final statistical guidance being made available today provides recommendations on how to use this approach if it is chosen.

This statistical guidance is one of a set of core guidances being developed to provide recommendations on how to meet the provisions of part 320. Taken together, these guidances are designed to address the studies that should be provided to document product quality BA/BE for all drug products regulated by CDER in accordance with the provisions of part 320.

This guidance is being issued consistent with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000). This Level 1 guidance document represents the agency's current thinking on the statistical approaches used in BA and BE studies. 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 an approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Documents Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 24, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01-2789 Filed 2-1-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10030]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* National Medicare Practitioner and Provider Survey; *Form No.:* HCFA-10030 (OMB# 0938-NEW); *Use:* 1. Health Care Financing Administration (HCFA) Program Safeguard Provider Education Project (Contract # 500-99-0013, Task Order 00001)—New

HCFA is conducting a national assessment of Medicare practitioner and provider (hereinafter referred to collectively as providers) educational needs. The purpose of the needs

assessment is to obtain information about the education or training related to Medicare claims submission that is required by providers to increase their rate of correct first-time submission of Medicare claims. Specifically, the needs assessment survey will seek information about: (1) What providers need to know about accurate claims submission, and (2) what they believe would be the best methods for obtaining that information.

Responses will be gathered from a random sample of fee-for-service providers representing both Medicare Part A (hospital-based outpatient clinics, emergency rooms, and ambulatory surgery units; home health care agencies; and skilled nursing facilities) and Medicare Part B (physician and non-physician) providers. The information gathered by the needs assessment survey will allow HCFA to develop effective education and training tools and resources that address identified provider needs and focus on the topics that providers indicated were most important for improving accuracy of claims submissions.

The needs assessment survey will be administered one time only. It will be mailed to 9,000 individual and organizational providers nationwide that render Medicare services. HCFA anticipates receiving approximately 7,200 responses. As an alternative to completing the paper survey, respondents will have the option of completing the survey electronically using a computer with an Internet connection. A toll-free telephone line will be available to respondents who have questions or need help completing the survey. HCFA is collaborating with national and State medical societies and organizations to make providers aware of the survey and the importance of their participation in the needs assessment process. Publicity about the survey prior to its dissemination, along with a follow-up mail reminder and conduct of follow-up phone calls to respondents after its dissemination, will increase the survey response rate. Burden estimates are as follows:

Respondents	Estimated Number of respondents	Number of responses per respondent	Average burden/response (in hours)
Survey	7,200	1	1/2