

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Online IRG	54	18	.3	292

Estimated Total Annual Burden Hours: 292.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 17, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99-21747 Filed 8-20-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2532]

Determination That Astemizole 10-Milligram Tablets Were Withdrawn From Sale for Safety Reasons

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that astemizole 10-milligram (mg) tablets (Hismanal) were withdrawn from sale for safety reasons. The agency will not accept or approve abbreviated new drug applications (ANDA's) for astemizole 10-mg tablets.

FOR FURTHER INFORMATION CONTACT:

Andrea C. Masciale, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of approved innovator drug products under an ANDA procedure. ANDA sponsors generally must show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's are not required to repeat the extensive clinical testing necessary to gain approval of an NDA. The only data from investigations required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). FDA may not approve an ANDA that does not refer to a listed drug (21 CFR 314.92(a)).

Astemizole 10-mg tablets (Hismanal) are the subject of approved NDA 19-402, currently held by Janssen

Pharmaceutica (Janssen). In 1988, FDA approved the NDA for Hismanal tablets for the relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria. On June 18, 1999, Janssen withdrew Hismanal tablets from sale in the United States. The agency's review of the withdrawal of astemizole 10-mg tablets (Hismanal) from the market has considered the sponsor's explanation of the basis for the withdrawal of the product and information available to the agency regarding Hismanal. The current evidence supports the conclusion under § 314.161 (21 CFR 314.161) that astemizole 10-mg tablets (Hismanal) were withdrawn from the market for safety reasons.

The agency has determined, under § 314.161, that astemizole 10-mg tablets (Hismanal) were withdrawn from the market for safety reasons. Accordingly, the agency will remove astemizole 10-mg tablets (Hismanal) from the "Orange Book" (§ 314.162). FDA will not accept or approve ANDA's that refer to this drug product.

Dated: August 13, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-21813 Filed 8-20-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2670]

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.

Dates and Time: The meeting will be held on November 2 and 3, 1999, from 8:30 a.m. to 5 p.m. Interested persons and organizations may submit written comments by September 30, 1999, to the Dockets Management Branch (address below).

Location and Addresses: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

Contact Person: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research, (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or the 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: Presentations and committee discussions will address issues related to testing for development of resistant human immunodeficiency virus (HIV-1), with an emphasis on its potential role in antiretroviral drug development. The primary objectives of these deliberations are to obtain advisory committee recommendations on the amount and type of resistance data needed to support both preclinical and clinical development of antiretroviral drugs and product labeling. This 2-day meeting will explore the following scientific issues: (1) Performance characteristics of genotypic and phenotypic assays, (2) definitions of antiviral drug resistance, (3) relationships between the development of mutations or reduced susceptibility and treatment outcome, and (4) available evidence supporting the clinical utility of testing for the development of antiviral drug resistance. In order to prepare presentations and discussions for the meeting, the agency is requesting interested persons to submit in writing the following types of relevant data, information, and views:

- Pre-clinical and/or clinical trial data on the relationship between the development of HIV mutations and changes in susceptibility to antiviral therapies.
- Prospective or retrospective clinical trial data on the relationship between genotype and/or phenotype and treatment outcome.
- Proposals for incorporating HIV resistance testing in clinical trial design.
- Proposals for utilizing information derived from HIV resistance testing to support product labeling.

These submissions should contain the following docket number, 99N-2670, and should be made to the Dockets Management Branch address provided previously in this document.

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 October 27, 1999. Oral presentation from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 3, 1999. Time allotted for each presentation may be limited. Written submissions may be made to the contact person by October 27, 1999. Those desiring to make formal oral presentations should notify the contact person before October 27, 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: August 13, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99-21729 Filed 8-20-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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: Oncologic 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 September 16 and 17, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Karen M. Templeton-Somers, 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 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 16, 1999, the committee will discuss: (1) New drug application (NDA) 21-053, UFT® (tegafur and uracil) Capsules, Bristol-Myers Squibb Co., indicated, with leucovorin calcium tablets, for the first-line treatment of metastatic colorectal cancer; and (2) NDA 50-772, Evacet™ (doxorubicin HCl liposome injection), The Liposome Co., Inc., indicated for the first-line treatment of metastatic breast cancer in combination with cyclophosphamide. On September 17, 1999, the committee will discuss: (1) NDA 20-262/S-033, TAXOL® (paclitaxel) Injection, Bristol-Myers Squibb Co., indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard combination therapy; and (2) biologics license application (BLA) 97-1001, Roferon®-A, Hoffman-La Roche Inc., indicated for use as adjuvant treatment of surgically resected malignant melanoma without clinical evidence of nodal disease, American Joint Committee on Cancer stage II (Breslow thickness > 1.5 millimeter, N0). In addition, FDA will provide an update on the preliminary results of EST 1690 (ECOG intergroup study of INTRON A for the adjuvant treatment of melanoma) for discussion by the committee.

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 September 8, 1999. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and between approximately 1:15 p.m. and 1:30 p.m. on September 16, 1999, and between approximately 8:15 a.m. and 8:45 a.m., and between approximately 1:15 p.m. and 1:30 p.m. on September 17, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 8, 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. After the scientific presentations, a 30-minute open public session will be conducted for interested persons who have submitted their