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Determination That Astemizole 10-Milligram Tablets Were Withdrawn From Sale for Safety Reasons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The Food and Drug Administration (FDA) has determined that astemizole 10-milligram (mg) tablets (Hismanal) were withdrawn from sale for safety reasons.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.