SUMMARY: The Administration on Aging announces that under the Statewide Legal Hotlines Program it will hold a competition to fund grant awards for seven to eight (7–8) projects at a federal share of approximately $100,000 to $175,000 per year for a project period of up to three (3) years.

Purpose of grant awards: The purpose of these projects is to establish, or expand or improve, Statewide Legal Hotlines aimed at advancing the quality and accessibility of the legal assistance provided to older persons.

Eligibility for grant awards and other requirements: Eligibility for grant awards is limited to public and/or non-profit agencies, faith-based and community-based organizations experienced in providing legal assistance to older persons.

Grantees are required to provide a 25% non-federal match.

DATES: The deadline date for the submission of applications is August 5, 2002.

ADDRESSES: Application kits are available by writing to the U.S. Department of Health and Human Services, Administration on Aging, Office of Consumer Choice and Protection, 330 Independence Ave., SW., Washington, DC 20201, by calling 202/619–1058 or online at: *www.aoa.gov/egrants.*

Applications must be mailed or hand-delivered to the Office of Grants Management at the same address. Instructions for electronic mailing of grant applications are available at *http://www.aoa.gov/egrants.*

Dated: May 8, 2002.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. 02–12003 Filed 5–13–02; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect Meeting: Cancelled

Name: National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect (NTFFASFAE) meeting-Cancelled.

Times and Dates: 8:30 a.m.–4:30 p.m., May 16, 2002, 8:30 a.m.–3 p.m., May 17, 2002.

Place: Doubletree Hotel Atlanta Buckhead, 3340 Peachtree Road, NE, Atlanta, Georgia 30326, telephone 404/231–1234, fax 404/231–5236.

Status: Meeting Cancelled. Published in the **Federal Register:** April 18, 2002, Volume 67, Number 75, Page 19190.

Contact Person for More Information: R. Louise Floyd, DSN, RN, Designated Federal Official, National Center on Birth Defects and Developmental Disabilities, CDC, 4700 Buford Highway, NE, (F–49), Atlanta, Georgia 30333, telephone 770/488–7372, fax 770/488–7361.

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 CDC and ATSDR.

Dated: May 8, 2002.

Alvin Hall,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02–11967 Filed 5–13–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0589]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extralabel Drug Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by June 13, 2002.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control Number 0910–0325)—Extension

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), (Public Law 103–396), amended the Federal Food, Drug, and Cosmetic Act to permit licensed veterinarians to prescribe extralabel use in animals of approved human and animal drugs. Regulations implementing provisions of AMDUCA are codified under part 530 (21 CFR part 530). A new provision under these regulations in § 530.22(b), permits FDA to establish a safe level for extralabel use in animals of an approved human or animal drug when the agency determines there is reasonable probability that this use may present a risk to the public health. The extralabel use in animals of an approved human or animal drug that results in residues exceeding a safe level is considered an unsafe use of a drug. In conjunction with the establishment of a safe level, the new provision permits FDA to request development of an acceptable residue detection method for an analysis of residues above any safe level established under part 530. The sponsor may be willing to provide the methodology in some cases, while in others, FDA, the sponsor and perhaps a third party, (e.g., a State agency or a professional association), may negotiate a cooperative arrangement to develop the methodology. If no acceptable analytical method is developed, the agency would be permitted to prohibit extralabel use of the drug.

In the **Federal Register** of January 28, 2002 (67 FR 3903), the agency requested comments on the collection of information. In response, FDA received one comment. The comment asked whether the proposed collection of information was necessary for the proper performance of FDA functions including whether the information would have practical utility. As detailed, FDA under this regulation is permitted to request development of an acceptable residue detection method for human or animal drugs used in an extralabel manner that could result in unsafe residues in edible products of the treated animal. If no acceptable analytical method is developed, FDA is permitted to prohibit extralabel use of the drug. Thus, this collection of information is necessary to permit licensed veterinarians to prescribe extralabel use of certain drugs.

The respondents may be sponsors of new animal drug(s), State or Federal

Government, or individuals. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The Center for Veterinary Medicine (CVM) has not found circumstances to require the establishment of a safe level and subsequent development of an analytical methodology. However, CVM believes there will be instances when an analytical methodology will be required.

Dated: May 3, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–11934 Filed 5–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0061]

Determination That IFEX (Ifosfamide for Injection), 1-Gram and 3-Gram Vials, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that IFEX (ifosfamide for injection), 1 gram (g) and 3 g, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ifosfamide.

FOR FURTHER INFORMATION CONTACT: Mitchell Weitzman, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5670.

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 drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, 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 version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data 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's 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 (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

IFEX is the subject of NDA 19–763, held by Bristol-Myers Squibb Co. (BMS). FDA approved NDA 19–763 on December 30, 1988. Used in combination with other approved antineoplastic agents, IFEX is indicated for third line chemotherapy of germ cell testicular cancer. In the IFEX clinical studies, it was observed that urotoxic side effects, especially hemorrhagic cystitis, were frequently associated with the administration of IFEX. The approved labeling for IFEX stated that IFEX ''should ordinarily be used in combination with a prophylactic agent for hemorrhagic cystitis, such as mesna.'' FDA separately approved BMS's NDA for MESNEX (mesna) Injection on December 30, 1988. BMS never marketed IFEX alone; instead, it elected to market IFEX exclusively in a combination package with MESNEX.

IFEX as a single agent is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. IFEX is also listed as part of a copackaged kit with MESNEX in the Orange Book's prescription drug product list. The relocation of IFEX as a single agent to the ''Discontinued Drug Product List'' coincided with a labeling modification on October 10, 1992, to reflect changes in storage conditions for IFEX and an approval of copackaging with MESNEX.

On January 31, 2001, Tom Stothoff submitted a citizen petition (Docket No. 01P–0061/CP1) to FDA under 21 CFR 10.30, requesting that the agency determine whether IFEX (as a single agent) was withdrawn from sale for reasons of safety or effectiveness. The petitioner seeks this determination in preparation for filing an ANDA for Ifosfamide for Injection, U.S.P.

On March 9, 2001, BMS filed a comment to the citizen petition requesting that FDA find that IFEX has not been withdrawn from sale and is not separately marketed by BMS for reasons of safety or effectiveness. With respect to safety and effectiveness, BMS argued that regardless of whether IFEX was withdrawn, FDA should deny the petitioner permission to file an ANDA for ifosfamide as a single agent because, as stated in the label, ifosfamide can only be administered safely in conjunction with a uroprotective agent such as mesna. BMS cited both the medical literature and the potential for urotoxic reactions if ifosfamide is used alone in support of this claim.

BMS contends that it has never withdrawn or ceased to market IFEX because it has marketed IFEX in a combination package with MESNEX since the time of their approval. However, IFEX was approved under its own NDA as a single agent. In previous instances (see, e.g., 61 FR 25497, May 21, 1996) (addressing a relisting request for glyburide tablets), FDA has concluded that never marketing an approved product is equivalent to withdrawing the drug from sale.