for the applicant's failure to conduct, complete, and report the study. Previously, status reports were only for postmarketing studies in pediatric populations. Section 601.28(c) (21 CFR 601.28(c)) requires that the status of postmarketing pediatric studies be reported under § 601.70 rather than under § 601.28 and, therefore, the information collection burden for postmarketing studies in pediatric populations is included under § 601.70. Respondents to this collection of information are the applicants holding approved applications for licensed biological products that have committed to conduct postmarketing studies. Based on information obtained from FDA's Center for Biologics Evaluation and Research computerized application and license tracking database, the agency estimates that approximately 44 applicants with 65 approved BLAs have committed to conduct approximately 223 postmarketing studies and would be required to submit an annual progress report on those postmarketing studies under § 601.70. Based on past experience with similar reporting requirements, the agency estimates that it takes an applicant approximately 24 hours (8 hours per study x 3) annually to gather, complete, and submit the appropriate information for each report (approximately two to four studies per report). Included in these 24 hours is the time necessary to prepare and submit two copies of the annual progress report of postmarketing studies to FDA under § 601.70(d).

In the **Federal Register** of June 26, 2003 (68 FR 38066), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden for 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
601.70(b) and (d)	44	1.5	65	24	1,560

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

Dated: January 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–943 Filed 1–15–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002N–0273]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

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.

DATES: Fax written comments on the collection of information by February 17, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, 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.

Title: 21 CFR Part 589—Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—(OMB Control Number 0910–0339)—Extension

Epidemiological evidence gathered in the United Kingdom suggests that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. Effective August 4, 1997, the FDA amended it regulations to create 21 CFR 589.2000 to regulate handlers of certain animal protein intended for use in ruminant feed. The regulation was designed to ensure that ruminant feed does not contain protein derived from mammalian tissue. It requires that firms that manufacture, blend, process or distribute both mammalian and nonmammalian materials intended for use in ruminant feed maintain written procedures to prevent commingling and cross-contamination of these materials.

Respondents to this collection of information are individuals or firms that manufacture, blend, process distribute, or use feed or feed ingredients that contain or may contain protein, that may be derived from mammalian tissue.

In the **Federal Register** of October 3, 2003 (68 FR 57468), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Sections	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
589.2000(e)(1)(iv)	400	1	400	14	5,600

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

The estimated number of recordkeepers (i.e., persons that separate mammalian and nonmammalian materials), is derived from inspections of firms handling animal protein intended for use in animal feed. The estimate of the time required for this recordkeeping requirement is based on agency communication with industry.

Dated: January 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1062 Filed 1–15–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of New Animal Drug Application; Ceftiofur

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provided revised susceptibility information for food-animal pathogens listed in the clinical microbiology section of labeling for ceftiofur hydrochloride injectable suspension.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail *jgotthar@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplement to NADA 140–890 which provides for the veterinary prescription use of EXCENEL (ceftiofur hydrochloride) RTU Sterile Suspension. The supplemental NADA provided updated susceptibility data for food-animal pathogens listed in the clinical microbiology section of labeling. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that this supplemental NADA is approved as of December 12, 2003. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 31, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–941 Filed 1–15–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting.

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages.

Dates and Times: February 9, 2004, 8:30 a.m.–5:30 p.m., February 10, 2004, 8:30 a.m.–5:30 p.m., February 11, 2004, 8:30 a.m.–4 p.m.

Place: The Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Status: The meeting will be open to the public.

Agenda: Agenda items will include, but not be limited to: Welcome; plenary session on healthcare disparities as it relates to the grant programs under the purview of the Committee with presentations by speakers representing the Department of Health and Human Services (DHHS), constituent groups, field experts and committee members. The following topics will be addressed at the meeting: What is the relationship between health disparities and underserved/unserved populations; what is the impact of health disparities on Title VII programs, what are Title VII programs doing in terms of legislative requirements, and what are the best practices to address health disparities employed by Title VII programs; and what are complementary programs doing to address health disparities, what are their best practices, and how can we collaborate with these partners to build on existing infrastructures and to maximize resources to address health disparities.

Proposed agenda items are subject to change as priorities dictate.

Public Comments: Public comment will be permitted at the end of the Committee meeting on February 9, 2004 and before lunch on February 10, 2004. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, with a copy of their presentation to: Jennifer Donovan, Deputy Executive Secretary, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 9–105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–8044.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The Division of State, Community and Public Health will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file a request in advance for a presentation, but wish to make an oral statement may register to do so at the Double Tree Hotel, Rockville, MD, on February 9, 2004. These persons will be allocated time as the Committee meeting agenda permits.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Jennifer Donovan, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 9–105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–8044.

Dated: January 12, 2004.

Tina M. Cheatham,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 04–1063 Filed 1–15–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.