*Respondents:* 59; *Total Annual Responses:* 59; *Total Annual Hours:* 118.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 8, 2004.

**John P. Burke, III,**

*Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 04–983 Filed 1–15–04; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003N–0295]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/ Processors With Interest in Exporting to Chile

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/ Processors With Interest in Exporting to Chile'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 8, 2003 (68 FR 58114), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0509. The approval expires on December 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: January 6, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–942 Filed 1–15–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003N–0267]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Studies for Licensed Biological Products; Status Reports

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information 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:** JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**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.

**Postmarketing Studies for Licensed Biological Products; Status Reports—(OMB Control Number 0910–0433)—Extension**

Section 130(a) of the Food and Drug Administration Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 506B of the act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated. The reporting requirements for applicants of approved new drug applications and abbreviated new drug applications are under §314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The collection of information requirements for § 314.81(b)(2)(vii) are approved under OMB control number 0910–0001. The reporting requirements for applicants of approved biologics license applications (BLAs) or supplements to an application are under § 601.70 (21 CFR 601.70). Section 601.70 requires applicants of approved biologics license applications or supplements to an application to submit to FDA postmarketing status reports for studies of clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology that are required by FDA or that an applicant of a BLA commits to conduct, in writing, at the time of approval of an application or a supplement to an application, or after approval of an application or a supplement. Information submitted in a status report for §601.70(b) is limited to that which is needed to sufficiently identify each applicant that has committed to conduct a postmarketing study, the status of the study that is being reported, and the reasons, if any,

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.