accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary. Samples and protocols are required by FDA to help ensure the safety, purity, or potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and specified biotechnology and specified synthetic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product. The following burden estimate is for protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of any licensed biological product. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. There are an estimated 329 manufacturers of licensed biological products, however, based on information obtained from FDA's database system, approximately 83 manufacturers submitted samples and protocols in fiscal years 1999 and 2000, under the regulations cited previously. FDA estimates that approximately 76 manufacturers submitted protocols under § 610.2 and 7 manufacturers submitted protocols under the regulations for the specific products. The total annual responses are based on the annual average of FDA's final actions completed in fiscal years 1999 and 2000, which totaled 6,747, for the various submission requirements of samples and protocols for biological products. The rate of final actions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the hours per response are based on the higher end of the estimate (rounded to 5 or 6 hours) because more information is generally required to be submitted in the protocol than under § 610.2.

In the **Federal Register** of December 27, 2002 (67 FR 79127), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment on the information collection in response to the 60-day notice.

The comment recommended that we should review the regulations under § 610.2(a) concerning lot release and consider modifications to reflect current manufacturing technology standards in light of industry's ability to control and test products to ensure identity, purity, and potency. The comment provided some suggestions to consider regarding the lot release requirements.

The comment's suggested regulatory revisions that pertain to provisions or matters that are outside the scope of the proposed information collection. Consequently, we decline to adopt the comment's recommendations.

FDA estimates the burden of this information collection 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
610.2	76	86.5	6,574	3	19,722
660.6(b)	4	28.5	114	5	570
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	2	29	58	5	290
Total	83		6,747		20,588

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

Dated: May 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12724 Filed 5–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0135]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers 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 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 Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 10, 2003 (68 FR 17655), 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 October 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12725 Filed 5–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0170]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is required, under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), to report annually in the **Federal Register** on the status of postmarketing study commitments made by sponsors of approved drug and biological products. This is the agency's first report on the status of the study commitments that sponsors have agreed to conduct and for which an annual status report on the study has been received by FDA.

FOR FURTHER INFORMATION CONTACT: Kim Colangelo, Center for Drug Evaluation and Research (HFD–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3937; or Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

Section 130(a) of the 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 human drugs and biological products. Section 506B provides FDA with additional authority to monitor the progress of a postmarketing study commitment that an applicant has been required or has agreed to conduct by requiring the applicant to submit a report annually providing information on the status of the postmarketing study commitment. This report must also include reasons, if any, for failure to complete the commitment.

On December 1, 1999 (64 FR 67207), FDA published a proposed rule providing a framework for the content and format of the annual progress report. The proposed rule also clarified the scope of the reporting requirement and timing for submission of the annual progress reports. The final rule, published on October 30, 2000 (65 FR 64607), modified annual report requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) by establishing § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The rule also created a new annual reporting requirement for biologics license applications (BLAs) by establishing § 601.70 (21 CFR 601.70). These regulations became effective on April 26, 2001. The regulations apply only to human drugs, including biological drugs. They do not apply to animal drugs or to licensed biological products that also meet the definition of a medical device.

Sections 314.81(b)(2)(vii) and 601.70 apply to postmarketing commitments made on or before enactment of the Modernization Act (November 21, 1997) as well as those made after that date. Sections 314.81(b)(2)(vii) and 601.70 require applicants of approved drugs and biological products to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study that is required by FDA (e.g., accelerated approval clinical benefit studies) or that they have committed to conduct either at the time of approval or after approval of their NDA, ANDA, BLA, or supplement. The status of other types of postmarketing commitments (e.g., those concerning chemistry, manufacturing, production controls, and studies conducted on an applicant's own initiative) are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. It should be noted, however, that applicants are required to report to FDA on these commitments made for NDAs and ANDAs under § 314.81(b)(2)(viii).

According to the regulations, once a postmarketing study commitment has been made, an applicant must report on the progress of the commitment on the anniversary of the product's approval until the postmarketing study commitment is completed or terminated and FDA determines that the postmarketing study commitment has been fulfilled or that the postmarketing study commitment is either no longer feasible or would no longer provide useful information. The annual progress report must include a description of the postmarketing study commitment, a schedule for completing the study commitment, and a characterization of the current status of the study commitment. The report must also provide an explanation of the postmarketing study commitment's status by describing briefly the postmarketing study commitment's progress. A postmarketing study commitment schedule is expected to include the actual or projected dates for: (1) Submission of the study protocol to FDA, (2) completion of patient accrual or initiation of an animal study, (3) completion of the study, and (4) submission of the final study report to FDA. The postmarketing study commitment status must be described in the annual report according to the following definitions:

- Pending: The study has not been initiated, but does not meet the criterion for delayed;
- Ongoing: The study is proceeding according to or ahead of the original schedule;
- Delayed: The study is behind the original schedule;
- Terminated: The study was ended before completion, but a final study report has not been submitted to FDA; or
- Submitted: The study has been completed or terminated, and a final study report has been submitted to FDA.

Databases containing information on postmarketing study commitments are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Information in this report covers any postmarketing study commitment that was made, in writing, at the time of approval or after approval of an application or a supplement to an application, including those required (e.g., to demonstrate clinical benefit of a product following accelerated approval) and those agreed to with the applicant. Information summarized in this report includes: (1) The number of applicants with open (uncompleted) postmarketing commitments, (2) the number of open postmarketing commitments, (3) the status of open postmarketing commitments as reported in § 314.81(b)(2)(vii) or § 601.70 annual