

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<sup>1</sup>

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

<sup>1</sup> 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.

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## 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