

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0021]

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	Center	D. Hawkins

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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**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 *[insert date 30 days after date of publication in the Federal Register]*.

**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: FDA Desk Officer, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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**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.

**Request for Samples and Protocols — (OMB Control Number 0910–0206) — Extension**

Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), FDA may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests prior to marketing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products: § 660.6 (21 CFR 660.6) (Antibody to Hepatitis B Surface Antigen), 660.36 (21 CFR 660.36) (Reagent Red Blood Cells), and 660.46 (21 CFR 660.46) (Hepatitis B Surface Antigen).

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by the Center for Biologics Evaluation and Research (CBER). After official release is no longer required, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol,

may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires that a protocol contain information including, but not limited to, manufacturing records, test records, and test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to FDA at the time of initial distribution of each lot.

Section 660.46(a) provides requirements for the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be 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 product meets the criteria for lot release that have been determined to be necessary by FDA. 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 the protocols that are 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 licensed biological products. 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 in this document. 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. Based on information obtained from FDA's database system, approximately 70 manufacturer's submitted samples and protocols in fiscal year (FY) 2005, under the regulations cited previously in this document. FDA estimates that 65 manufacturers submitted protocols under § 610.2, and 4 manufacturers submitted protocols under the regulations (§§ 660.6 and 660.46) for the other specific products. FDA received no submissions under § 660.36, however FDA is using the estimate of one protocol submission in the event one is submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2005, which totaled 4,930, for the various submission requirements of samples and protocols for the licensed 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) since more information is generally required to be submitted in the protocol than under § 610.2.

In the **Federal Register** of January 24, 2006 (71 FR 3856), 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<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
610.2	65	74.1	4,816	3	14,448
660.6(b)	3	26	78	5	390
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	1	35	35	5	175
Total	70				15,019

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: JUN 23 2006  
June 23, 2006.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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