

OMB INFORMATION COLLECTION  
SUPPORTING STATEMENT  
0910-0168

Shipment of a Blood Product Prior to Completion of Testing for Hepatitis B Surface Antigen (HBsAg); and Shipment of Blood Products Known Reactive for HBsAg

**JUSTIFICATION**

**1. Circumstances Making the Collection of Information Necessary**

The Food and Drug Administration (FDA) is requesting an extension of OMB Control No. 0910-0168 and OMB approval of the information collection requirements in 21 CFR Parts 610 (Tab A), listed below:

21 CFR 610.40(b)(4)	Reporting	Requires a collection facility to notify FDA of any emergency or preapproved shipments of any blood products intended for further manufacturing that are untested or incompletely tested for HBsAg.
21 CFR 610.40(d)(1)(v)	Reporting	Requires a collection facility to notify FDA of each shipment, or semi-annually for repetitious shipments, of HbsAg reactive source blood, plasma, or serum for manufacturing into hepatitis B vaccine or into a licensed in vitro diagnostic biological product.
21 CFR 610.40(d)(2)(iv)	Reporting	Requires a collection facility to notify FDA of each shipment of HbsAg reactive source blood, plasma, or serum for manufacturing unlicensed in vitro diagnostic biological products, including clinical chemistry control reagents.

Under sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262 and 42 U.S.C. 264, Tab B), FDA prescribes standards designed to ensure the safety, purity, potency, and effectiveness of biological products including blood and blood components and to prevent the transmission of communicable diseases. To accomplish this, FDA requires, among other things, that each unit of Whole Blood or Source Plasma to be tested by a licensed serologic test for hepatitis B surface antigen (HBsAg). Blood and blood products may not be shipped until the collection facility receives the written test results. However, preapproved or emergency shipments of blood products untested, incompletely tested, or known reactive for HbsAg may be permitted by FDA for further manufacturing provided FDA is notified of such shipments.

**2. Purpose and Use of the Information**

The reporting requirements inform FDA of the shipment of potentially infectious biological products that may be capable of transmitting disease. It is used by FDA inspectors and the Center for Biologics Evaluation and Research staff to monitor the collection, proper use, distribution, and disposal of potentially reactive HbsAg blood products. The reporting requirements serve preventative and remedial purposes. Without this information FDA could not discharge its statutory responsibility for protecting the public's health.

### **3. Use of Information Technology and Burden Reduction**

Establishments may use computer tapes, discs, microfiche or microfilm in lieu of hard copy records. FDA does not require completion of any standardized forms to fulfill these reporting requirements. FDA is not aware of any other improved technology to reduce the reporting burden.

### **4. Efforts to Identify Duplication and Use of Similar Information**

FDA is the only agency that requests this information. There is no similar kind of information available from any other source.

### **5. Impact on Small Businesses or Other Small Entities**

FDA believes that its duty requires the equal application of the regulations to all enterprises. FDA must enforce uniform standards of collection, processing and handling of blood and blood components throughout the country to ensure that these products are safe, pure, potent and effective for their intended use. Consequently, the regulations must apply equally to both small and large manufacturers to adequately protect the Nation's health. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. CBER's Office of Communication, Training, and Manufacturer's Assistance provides assistance to small businesses subject to FDA's regulatory requirements.

### **6. Consequences of Collecting the Information Less Frequently**

In the case of the emergency shipments affected by 610.40(b), emergency shipments for manufacturing purposes are infrequent. Consequently, a collecting facility making one or no emergency shipment per year would not significantly benefit from provisions allowing annual or semi-annual reports. The potential benefit of immediate reporting exceeds any slight benefit accruing from delayed reporting. In the case of the provision in 610.40(d)(1)(v), many of these shipments are made by establishments which routinely collect and ship reactive products. The current regulation permits semi-annual reporting by collection facilities that make repetitive shipments. Less frequent collection of information or other methods of reducing the frequency of collection would negate the purpose of on-site inspection of products, procedures, and records. It would not provide the necessary information needed by FDA to ensure safety, purity, and potency of blood and blood components and to protect the public health of the nation.

There are no technical or legal obstacles to reducing the burden.

### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances for the collection of the information requirements.

### **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency**

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment on the information collection provisions was published in the **Federal Register** of September 7, 2000 (65 FR 54282, Tab C). *No comments were received from the public.*

**9. Explanation of Any Payment or Gift to Respondents**

No payment or gift was provided to respondents.

**10. Assurance of Confidentiality Provided to Respondents**

The confidentiality of information received by FDA would be consistent with the Freedom of Information (FOI) Act and the agency's regulations under 21 CFR Part 20.

**11. Justification for Sensitive Questions**

Questions of a sensitive nature are not applicable to this information collection.

**12. Estimates of Hour Burden Including Annualized Hourly Costs**

The estimated annual burden for this information collection is 11.5 hours.

Estimated Annual Reporting Burden					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
610.40(b)	1	1	0.5	0.5	0.5
610.40(d)	12	1.83	22	0.5	11
Total					11.5

The respondents for this information collection are the blood collection facilities that ship hepatitis B reactive products. Only a few firms are actually engaged in shipping hepatitis B reactive products and making the reports required by §610.40. Also, there are very few to no emergency shipments per year related to further manufacturing and the only product currently shipped prior to completion of hepatitis B testing is Source Leukocytes, a licensed product. Shipments of Source Leukocytes are preapproved under the biological license application and do not require notification of shipment. Currently, there have been no respondents reporting emergency or preapproved shipments (§610.40(b)). However, FDA is listing one report per year for emergency or preapproved shipments to account for the possibility of future emergency shipments. The report involves a brief letter and an enclosure. The letter identifies who is making the shipment, to whom shipped, the nature of the emergency, the kind and quantity shipped, and date of shipment. The enclosure is a copy of the shipper's written standard operating procedures for handling, labeling, storage, and shipment of infectious product. The burden for development and maintenance of standard operating procedures is approved under OMB No. 0910-0116. The estimated number of respondents and total annual responses under §610.40(d) are based on the annual average of reports submitted to FDA in 1999. The notice for this provision on reactive product shipment is limited to information on the identity of the kind and amount of source material shipped; the name and address of the consignee; the date of shipment; and the manner in which the source material is labeled. The hours per response are based on past FDA experience.

**Cost to Respondents**

The estimated annual cost to respondents is \$402.50.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	11.5	\$35	\$402.50

The cost estimate is based on preparation of the report by a supervisor, at a pay rate of \$35/hour. These salary estimates include benefits but no overhead costs.

**13. Estimate of Other Total Annual Cost Burden to Respondents or Record-keepers**

There are no capital and start-up, or operation, maintenance and purchase costs associated with the collection of information requirements.

**14. Annualized Costs to the Federal Government**

The estimated annualized cost to the Federal Government is \$379.50. This estimate is based on a FDA reviewer at an average grade scale of GS-12/5 (\$33/hour) who reviews reports submitted by the collection facilities. These salary estimates include benefits but no overhead costs.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Reviewer	23	0.5	\$33	\$379.50

**15. Explanation of Program Changes or Adjustments**

The estimated total annual burden for this information collection requirement was 26 hours in 1997. The current decrease to 11.5 burden hours is mostly attributed to a decrease in the number of annual responses from the collection facilities.

**16. Plans for Tabulation and Publication and Project Time Schedule**

There are no tabulated results to publish for this information collection.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

**18. Exception to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to Item 19 of OMB Form 83-I.