B surface antigen (HBsAg). Section 610.40(b)(4) (21 CFR 610.40(b)(4)) permits preapproved or emergency shipments of blood products for further manufacturing before the test for HBsAg is completed. To obtain approval for such shipments, the collection facility must submit a description of the control procedures to be used by the collection facility and manufacturer. Proper control procedures are essential to ensure the safe shipment, handling, and quarantine of untested or incompletely tested blood products, communication of test results, and appropriate use or disposal of the blood products based on the test results. Section 610.40(d)(1)(v) and (d)(2)(iv) requires that a collection facility notify FDA of shipments of HBsAg reactive source blood, plasma, or serum for manufacturing into hepatitis B vaccine and licensed or unlicensed in vitro diagnostic biological products, including clinical chemistry control reagents. The reporting requirements inform FDA of the shipment of potentially infectious biological products that may be capable of transmitting disease. FDA's monitoring of such activity is essential should any deviations occur that may require immediate corrective action to protect public safety.

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 a licensed product, Source Leukocytes. Shipments of Source Leukocytes are preapproved under the product license applications 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 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 hours per response are based on past FDA experience.

In the **Federal Register** of September 7, 2000 (65 FR 54282), the agency requested comments on the proposed collection of information. No significant comments were received.

FDA estimates the burden of 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
610.40(b) [2]	1	1	0.5	0.5	11
610.40(d) [3]	12	1.83	22	0.5	11.5

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

[2] The notice 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 shippers written standard operating procedures for handling, labeling storage, and shipment of contaminated (contagious) product. The burden for development and maintenance of standard operating procedures is approved under OMB Control No. 0910–0116.

[3] The notice of 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.

FDA has calculated no additional burden in this information collection package for the labeling requirements in § 610.40(d) because the information and statements on the label necessary for public disclosure and safety are provided by FDA in these regulations. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: December 5, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31481 Filed 12–8–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the following meetings of SAMHSA Special Emphasis Panels I in December 2000.

A summary of the meetings and a roster of the members may be obtained from: Ms. Coral Sweeney, Review Specialist, SAMHSA, Office of Policy and Program Coordination, Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: 301–443–2998.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meetings will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, these meetings are concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b© (6) and 5 U.S.C. App.2, § 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Date: December 11–15, 2000.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Closed: December 11, 2000 to Adjournment.

Panel: Community Action Grants, PA 00–003 2 Committees.

Contact: Diane McMenamin, Director, Division of Extramural Activities, Policy and Review, Parklawn Building, 5600 Fishers Lane, Room 1789, Rockville, Maryland 20857.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: November 27, 2000.

Coral Sweeney,

Review Specialist, Substance Abuse and Mental Health Services Administration.

[FR Doc. 00–31409 Filed 12–8–00; 8:45 am]

BILLING CODE 4162–20–U