DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Michael K. Hartzer, Ph.D., Oakland University: Based on the report of an investigation conducted by Oakland University and additional analysis conducted by ORI during its oversight review, PHS found that Dr. Hartzer, former Associate Professor of Biomedical Sciences, Eye Institute, Oakland University, engaged in scientific misconduct by falsifying the status of support materials in eight National Eye Institute (NEI), National Institutes of Health (NIH), grant applications.

Specifically, Dr. Hartzer falsified the status of 11 manuscripts in eight grant applications by listing them as ''accepted'' or ''in press'' when the papers had either not been subsequently published or had been rejected. The repetition of these actions over several years indicates a pattern of knowingly misrepresenting the research record.

Dr. Hartzer has accepted the PHS finding and has entered into a Voluntary Exclusion Agreement with PHS in which he has voluntarily agreed for a period of three (3) years, beginning on November 20, 2000:

(1) That he must submit with each PHS research application, continuing application, or report a statement of certification, endorsed by an institutional official, that all manuscripts or publications are properly and accurately cited in the application; the institution must also submit a copy of the certification to ORI;

(2) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris Pascal,

Director, Office of Research Integrity.

[FR Doc. 00–31361 Filed 12–8–00; 8:45 am]

BILLING CODE 4155–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1506]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended For Immediate Slaughter'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 21, 2000 (65 FR 57193), 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 0910–0453. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: December 5, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31480 Filed 12–8–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1467]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by January 10, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Shipment of a Blood Product Prior to Completion of Testing for Hepatitis B Surface Antigen (HBsAg)—(21 CFR 610.40(b)); and Shipment of Blood Products Known Reactive for HBsAg—(21 CFR 610.40(d)) (OMB Control Number 0910–0168)—Extension

Under sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262 and 264), 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 be tested by a licensed serologic test for hepatitis

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