

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. Hartzler, 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. Hartzler, 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. Hartzler 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. Hartzler 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.

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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]

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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