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 Acting Assistant Secretary for Health have taken final action in the following case:

Bernd Hoffmann, Ph.D., University of Medicine and Dentistry of New Jersey: Based on two inquiry/investigation reports from the University of Medicine and Dentistry of New Jersey (UMDNJ) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Bernd Hoffmann, Ph.D., former Postdoctoral Fellow and Adjunct Assistant Professor, Department of Pharmacology at UMDNJ, engaged in scientific misconduct in research supported by National Institutes of Health (NIH) grant 2 R01 GM052309–05.

PHS found that Dr. Hoffmann engaged in scientific misconduct by falsifying and fabricating research data in a manuscript entitled ''LIS1/NUDF and CLIP–170 are required for dynein-mediated vesicle transport on microtubules'' that had been submitted to the *Journal of Cell Biology* (JCB), but was withdrawn before publication. Specifically, Respondent:

- Falsified data values on the second line from the bottom of Table IV; for example, the correct number under ''Bound'' in the first column was only one-third of that shown (325) in the manuscript;
- falsified data by erasing a band of approximate molecular weight 15KD from Figure 5A in the manuscript; and
- falsified a related movie film available on the Internet by altering the movement of the vesicles.

PHS also found that Dr. Hoffmann engaged in scientific misconduct by falsifying and fabricating research data in a published paper entitled ''The LIS1-related Protein NUDF of *Aspergillus nidulans* and its Interaction Partner NUDE Bind Directly to Specific Subunits of Dynein and Dynactin and to Alpha- and Gamma-Tubulin'' that had been published in the *Journal of Biological Chemistry* (JBC) at 276:38877–38884, 2001. Specifically, Respondent:

- Falsified Figure 5A left, Western blot with the alpha tubulin antibody for incubated proteins (+E+gamma+alpha); the lower right band was reused twice in Figure 2A. In Figure 5A, it was used as gamma tubulin band for the coprecipitation experiment with NUDF-Prot.S and as NUDE for the coprecipitation experiments with NUDG (CDLC)-Flag;
- falsified Figure 5A left, NUDF Western blot with the alpha tubulin antibody for incubated proteins (+E+gamma+alpha); the lower left band was reused in Figure 2A as alpha tubulin in the coprecipitation experiment with NUDF-Prot.S; and
- falsified Figure 4A left, NUDF and for the interaction between the two proteins NUDA and NUDF, pulled out with NUDA-FLAG-agarose, had been used at several other places such as Figure 5A left, left gamma tubulin band, Figure 5B left, NUDE band for the interaction E + alpha, and Figure 5B right, NUDE band for the interaction E + K (ARP1).

Dr. Hoffmann has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed for a period of three (3) years, beginning on January 30, 2004:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as ''covered transactions'' as defined in the debarment regulations at 45 CFR part 76;

(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; and

(3) to draft a letter of retraction and send it to ORI along with the signed Agreement. The draft letter requested the retraction of the JBC paper published at 276:38877–38884, 2001 and stated that he falsified and fabricated data in Figures 2A, 4A, 5A, and 5B. Upon ORI approval of the draft letter, Respondent agreed to send the final retraction letter to the Editor of JBC.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. 04–3865 Filed 2–23–04; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: National Directory of New Hires.

OMB No.: 0970–0166.

Description: Public Law 10–193, the ''Personal Responsibility and Work Opportunity Reconciliation Act of 1996,'' requires the Office of Child Support Enforcement (OCSE) to operate a National Directory of New Hires (NDNH) to improve the ability of state child support enforcement agencies to locate noncustodial parents and collect child support across state lines. The law requires employers to report newly hired employees to states. States are then required to periodically transmit new hire data received from employers to the NDNH, and to transmit wage and unemployment compensation claims data to the NDNH on a quarterly basis. Federal agencies are required to report new hires and quarterly wage data directly to the NDNH. All data is transmitted to the NDNH electronically.

Respondents: Employers, State Child Support Enforcement Agencies, State Employment Security Agencies, Federal Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
New Hire: Employers Reporting Manually	5,166,000	3.484	0.417 hours (2.5 minutes)	750,531
New Hire: Employers Reporting Electronically	1,134,000	37.037	0.0028 hours (1 second)	11,760
New Hire: States	54	83.333	266.668 hours	1,200,001

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Quarterly Wage and Unemployment Compensation	54	8	0.033 hours (2 minutes)	14
Multistate Employers' Notification Form	2,508	1	0.050 hours (3 minutes)	125
Estimated total annual burden hours				1,962,431

SUPPLEMENTARY INFORMATION: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *rsargis@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *katherine_t._astrich@omb.eop.gov*.

Dated: February 19, 2004.

Robert Sargis,

Reports Clearance Office.

[FR Doc. 04–3948 Filed 2–23–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0046]

Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on orphan drugs.

DATES: Submit written or electronic comments on the collection of information by April 26, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Orphan Drugs—21 CFR Part 316 (OMB Control Number 0910–0167)

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa through 360dd) give FDA statutory authority to: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the act and sets forth procedures FDA will use in administering the act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application, which includes requirements than an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the