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#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Who Should Attend?

This announcement is directed towards professionals involved in the manufacture, control, and regulation of pharmaceutical products who will benefit from these workshops, including process/production engineers, manufacturing personnel, quality assurance/quality control and regulatory affairs professionals, consultants, regulatory investigators and CGMP compliance officials. Other entities or individuals may also be interested in attending.

###### B. Where and When Will These Workshops Be Held?

The location and times for the two workshops are listed in table 1 of this document.

TABLE 1.—WORKSHOP LOCATION AND SCHEDULES

Workshop Address	Dates and Local Times
Ying Jie Convention Center, Peking University, Beijing, China	December 5 through 7, 2005, from 9 a.m. to 5 p.m. each day.
Ying Jie Convention Center, Peking University, Beijing, China	April 24 through 26, 2006, from 9 a.m. to 5 p.m. each day.

###### C. How Can I Participate?

You can participate in person. Anyone interested in the GMP workshops can register through the contact person in the **FOR FURTHER INFORMATION CONTACT** section of this document.

###### D. Is There a Registration Fee for These Workshops?

Yes, a registration fee of \$440 is required for this workshop. This registration fee includes workshop reference materials and meals. Government employees qualify for a discounted rate of \$120.

###### E. How Can I Get Additional Information?

The notice of participation form, information about the workshops, and other related documents are available from the contact person in the **FOR FURTHER INFORMATION CONTACT** section of this document or from the Internet at

<http://www.fda.gov/cder/meeting/CTP2005.htm>.

##### II. Background Information

###### A. Why Is FDA Cosponsoring These Workshops?

FDA is cosponsoring these 3-day workshops to provide information and training opportunities for industry as well as CGMP compliance officials.

###### B. What Will Be Covered?

The workshops will provide information on specific topics designed to educate and guide participants on methodologies and implementation of CGMP as applied to quality drug manufacturing. Presentations by both FDA and industry will provide a regulatory and practical perspective on the current relevant critical topics.

Dated: August 24, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Indian Health Service

##### **Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service (IHS) Background Investigations of Individuals in Position Involving Regular Contact With or Control Over Indian Children OPM-306.**

**AGENCY:** Indian Health Service, HHS.

**SUMMARY:** The Department of Health and Human Services, as part of its continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the IHS is providing a 60-day advance opportunity for public comment on a proposed extension of current information collection activity to be submitted to the office of Management and Budget for review.

##### Proposed Collection

*Title:* 0917-0028, "IHS Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over Indian Children" OPM-306.

*Type of Information Collection Request:* Extension, without revision, of currently approved information collection, 0917-0028, "IHS Background Investigations of Individuals in Position Involving Regular Contact With or Control Over Indian Children" OPM-306.

*Form Number:* OF-306.

*Forms:* Declaration for Federal Employment.

*Need and Use of Information Collection:* This is a request for approval of collection information required by section 408 of the Indian Child Protection and Family Violence Prevention Act, Public Law 101-630, 104 Stat. 4544, 25 U.S.C. 3201-3211. The IHS is required to compile a list of all authorized positions within the IHS where the duties and responsibilities involve regular contact with, or control over, Indian children; and to conduct an investigation of the character of each individual who is employed, or is being considered for employment in a position having regular contact with, or control over, Indian children. Section 3207(b) of the Indian Child Protection and Family Violence Prevention Act was amended by section 814 of S. 3031, the Native American Laws Technical Corrections Act of 2000, which requires that the regulations prescribing the minimum standards of character ensure that none of the individuals appointed to positions involving regular contact with, or control over Indian children have been found guilty of, or entered a plea of nolo contendere or guilty to any felonious offense, or any of two or more misdemeanor offenses under Federal, State, or tribal law involving crimes of violence; sexual assault, molestation, exploitation, contact or prostitution; crimes against persons; or offenses committed against children. In addition, 42 U.S.C. 13041 requires each agency of the Federal Government, and every facility operated by the Federal Government (or operated under contract with the Federal Government), that hires (or contracts for hire) individuals involved with children under the age of 18 or child care services to assure that all existing and newly-hired employees undergo a criminal history background check. The background is to be initiated through the personnel program of the applicable Federal agency. This section requires employment applications for individuals who are seeking work for an

agency of the Federal Government, or for a facility or program operated by (or through contract with) the Federal Government, in positions involved with the provision to children under the age of 18 or child care services, to contain

a question asking whether the individual has ever been arrested for or charged with a crime involving a child.

*Affected Public:* Individuals and households.

*Type of Respondents:* Individuals.

The table below provides the estimated burden hours for this information collection:

#### ESTIMATED BURDEN HOURS

42 CFR Part 36	Estimated number of respondents	Responses per respondent	Average burden hour per response *	Total annual burden hours
Addendum to OF 306 Declaration for Federal Employment .....	2,000	1	0.25 (15 mins)	500

\* For ease of understanding, burden hours are also provided in actual minutes.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

*Request For Comments:* Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Send Comments and Requests For Further Information:* Send your written comments and requests for more information on the proposed collection or requests to obtain a copy of the data collection instrument(s) and instructions to: Mrs. Chris Rouleau, IHS Reports Clearance Officer, 801 Thompson Avenue, Rockville, MD 20852, call non-toll free (301) 443-5938, send via facsimile to (301) 443-2316, or send your E-mail requests, comments, and return address to: [crouleau@hqe.ihs.gov](mailto:crouleau@hqe.ihs.gov).

*Comment Due Date:* Your comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: August 24, 2005.

**Robert G. McSwain,**

*Deputy Director, Indian Health Service.*

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**BILLING CODE 4165-16-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; Survey of NIGMS Minority Opportunities in Research (MORE) Division Institutional Program Directors

*Summary:* Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of General Medical Sciences (NIGMS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 22, 2005, pages 8594-8595 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Proposed Collection: Title:* Survey of NIGMS Minority Opportunities in Research (MORE) Division Institutional Program Directors. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* NIGMS provides research and research training

support in the basic biomedical sciences through a variety of programs and grant mechanisms. Several of these programs are targeted toward support of underrepresented minority students at various educational levels and research faculty at minority-serving institutions. Although significant resources are dedicated to funding these programs, there is a lack of quantitative information on program outcomes. This proposed one-time survey is part of a larger study that will provide NIGMS with the high-quality data needed to evaluate the educational outcomes and research activity of students and faculty who are supported by NIGMS training and research support programs. Data on student enrollment and highest degree received will be collected from institutional program directors in the following programs: Minority Access to Research Careers Undergraduate Student Training in Academic Research (U\*STAR), Minority Biomedical Research Support Initiative for Minority Student Development (IMSD), and Minority Biomedical Research Support Research Initiative for Scientific Enhancement (RISE). Other data will be collected from existing sources, including grant records and Medline databases. Taken together, the data will be used as a baseline for future assessments, as well to further develop current programs and in the creation of proposals for new initiatives in minority recruitment and training. These results will be reported to the National Advisory General Medical Sciences Council (NAGMSC) and shared with the community of NIGMS grantees. *Frequency of Response:* Once. *Affected Public:* Individuals or households; Not-for-profits. *Type of Respondents:* Training grant program directors.

The annual reporting burden is as follows: