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Dated: May 19, 1999.

John L. Williams,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention
(CDC).*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 99139]

Grants for Minority Health Statistics Dissertation Research; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 1999 funds to fund Grants for Minority Health Statistics Dissertation Research which was published in the **Federal Register** on May 18, 1999, (Vol. 64, No. 95, Pages 26975-26977). The notice is amended as follows:

On page 26975, Second Column, under Section C. Availability of Funds, delete the last two sentences. Add the following sentence:

The awards will be made for a 12-month budget/project period.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1387]

Agency Information Collection Activities; Agency Emergency Processing Request Under OMB Review; Survey of Licensed Biologics Manufacturers and Registered Blood Establishments for Year 2000 Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of

information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns a survey of manufacturers of biological products, including both licensed biologics manufacturers and registered blood establishments, to obtain information about the Year 2000 compliance status of the facilities used to manufacture regulated products. The information will be made available to the public via FDA's web site.

DATES: Submit written comments on the collection of information by June 1, 1999.

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: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. FDA is requesting certain information on the Year 2000 compliance status of biologics manufacturing processes. This information is needed immediately in order to allow the agency to: (1) Assess the impact of the Year 2000 problem on the continued availability of an adequate supply of safe and effective biological products, (2) properly advise the healthcare industry and U.S. public regarding the preparedness of the biologics industry, and (3) assess the need for additional government actions to address potential supply disruptions. This information is essential to the mission of the agency. The potential existence of the Year 2000 problems in the biologics industry could pose potentially serious health and safety consequences. The use of normal clearance procedures would prolong the time needed to assess the Year 2000 compliance by regulated industry.

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.

Title: Survey of Licensed Biologics Manufacturers and Registered Blood Establishments for Year 2000 Compliance

Facilities will be asked to provide information about their Year 2000 readiness. They will also be asked if they have established contingency plans to address potential Year 2000 related problems and if those contingency plans address issues with foreign suppliers. The request will ask licensed manufacturers if they expect to file supplements to their applications for Year 2000 related manufacturing changes or as part of contingency planning. The survey will also request manufacturers to provide information about their plans and capability to increase production should there be an increased demand for their products. The survey will request that respondents identify contact information, including, where available, the address of a web site where more information about their Year 2000 activities can be found. The respondents will be able to provide information via facsimile or paper copy.

FDA intends to use the survey information to provide information to health care providers and the general public on the status of Year 2000 readiness of biologics facilities. FDA needs this information in a timely manner so as to have sufficient time in which to analyze the data received and make the information available.

Respondents: Licensed biologics manufacturers and registered blood establishments.

FDA estimated the number of respondents through its licensing and registration data bases. FDA estimates that it will take firms an average of 18 hours to collect, prepare, and submit the requested information.

FDA estimates the burden for this collection of information as follows: