programs, principally but not limited to food safety and applied nutrition (e.g., microbial pathogens, natural toxins, chemical contaminants, and food composition and nutrition); and (3) enhance risk communication, through outreach and public information programs, that will help the mass media and consumers understand and act on public health concerns. Innovative research and outreach efforts, made possible by the supplemental funding, will complement existing efforts under FDA's current cooperative agreement with the UMCP and will provide public health officials with the appropriate knowledge to formulate regulatory decisions and enhanced capabilities to communicate with their stakeholders.

V. Substantive Involvement by FDA

All terms and conditions of the current award shall remain in full force and effect for the supplemental awards.

VI. Review Procedure

The application submitted by the UMCP will undergo a noncompetitive, dual peer review. The application will be reviewed for scientific and technical merit by a panel of experts based on applicable evaluation criteria. If the application is recommended for approval it will then be presented to the National Advisory Environmental Health Sciences Council.

VII. Reporting Requirement

All terms and conditions of the current award shall remain in full force and effect for the supplemental awards.

VIII. Mechanism of Support

Support will be in the form of supplements to FDA's cooperative agreement with the UMCP. This agreement will be subject to all policies and requirements that govern the research grant program of the Public Health Service, including provisions of 42 CFR part 52 and 45 CFR part 74.

Dated: July 15, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–18929 Filed 7–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2096]

Draft ''Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations.'' The draft guidance document is intended to provide sponsors and manufacturers FDA's current thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and implementing regulations.

DATES: Written comments may be submitted at any time, however, comments should be submitted by October 25, 1999, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–940), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations.''

In the **Federal Register** of December 29, 1992 (57 FR 62076), FDA published the orphan drug regulations final rule. The final rule established in part 316 (21 CFR part 316) regulations that prescribe certain incentives for the development of ''orphan drugs,'' drugs which are intended for use in rare diseases or conditions. One of the incentives for orphan drug development is to obtain exclusive approval for the pioneer product for a period of 7 years during which no approval will be given to a subsequent sponsor of the same drug product for the same indication unless it proves to be clinically superior, as defined in § 316.3(b)(3). In determining whether or not two products would be considered the same, FDA recognized that different criteria were necessary for macromolecules versus small molecules (§ 316.3(b)(13)). Macromolecules include a variety of structures including proteins, nucleic acids, carbohydrates and closely related, complex, partly definable drugs such as vaccines or surfactants. The current definition of sameness for protein drugs (§ 316.3(b)(13)(ii)(A)) however, does not consider the unique nature of antibodies. The draft document is intended to describe FDA's thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and its implementing regulations.

This draft guidance document represents the agency's current thinking on the interpretation of the orphan drug regulations as they pertain to monoclonal antibodies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written

comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by October 25, 1999, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: July 14, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–18928 Filed 7–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Institutes of Health Undergraduate Scholarship Program for Individuals From Disadvantaged Backgrounds

SUMMARY: In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director (OD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: The National Institutes of Health Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds (UGSP). Type of Information Collection Request: Extension of OMB No. 0925–0438, expiration date of November 30, 1999. Need and Use of Information Collection: The UGSP is authorized by § 487D of the Public Health Service (PHS) Act (42 U.S.C. 288–2), as amended by the NIH Revitalization Act of 1993 (Pub. L. 103–43). This program intends to provide scholarships, in an amount not to exceed $20,000 per academic year, toward expenses associated with full-time attendance at an accredited undergraduate institution, including tuition and reasonable educational and living expenses. For each year of scholarship support from the NIH, the recipient agrees to two service obligations or pay-back requirements: (1) ten consecutive weeks of pay-back as a full-time NIH employee during the months of June–August during the academic year (in-school service obligation) and (2) one year (12 months) of pay-back as a full-time NIH employee after graduation from the undergraduate institution (post-graduation service obligation. The post-graduation service obligation or pay-back requirement may be deferred, at the request of the scholarship recipient and with the approval of the Secretary, Department of Health and Human Services, during continuous period of graduate or medical/dental/veterinarian school training. The UGSP is designed to provide an incentive to undergraduate students from disadvantaged backgrounds to pursue studies which will prepare them for careers in biomedical research at the NIH. The information proposed for collection will be used to determine an applicant's eligibility for participation in the UGSP. Frequency of Response: Initial application and annual renewal application. Affected Public: Applicants (High School or undergraduate level students), Undergraduate Institutions. Type of Respondents: The UGSP application consists of two parts: Part I (Information About the Applicant) is completed by the applicant; and Part II (Verification) is completed by the Undergraduate Institution. The annual reporting burden estimates are as follows:

Type of respondent	Number of respondents	Numbr of responses per respondent	Average burden per response (Hrs)
Applicant	500	1	3.0
Undergraduate Institution	500	1	0.5

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.

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Marc S. Horowitz, J.D., Director, Office of Loan Repayment and Scholarship, Office of Intramural Research, OD, NIH, 7550 Wisconsin Avenue, Room 604, Bethesda, MD 20814–9121, or call non-toll-free number (301) 402–5666 or E-mail your request, including your address to: MHorowitz@nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before September 24, 1999.