public review and comment. Interested persons may, on or before December 2, 1996 submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: October 16, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–27994 Filed 10–30–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0344]

Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use.'' This guidance document was prepared by the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). On May 14, 1996, FDA published a final rule that amended the biologics regulations to eliminate the establishment license application (ELA) for manufacturers of certain products. Instead, a sponsor may submit a biologics license application that includes a chemistry, manufacturing, and controls (CMC) section. This guidance document is intended to assist applicants in the preparation of the CMC information for marketing applications for certain specified products, including therapeutic recombinant deoxyribonucleic acid (DNA)-derived products or monoclonal antibody products for in vivo use, as well as those recombinant DNA-derived products regulated using a new drug application submitted to CDER.

DATES: Written comments may be submitted at any time, however, to ensure comments are considered for the next revision they should be submitted by January 29, 1997.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or Monoclonal Antibody Product for In Vivo Use'' to the Manufacturers Assistance and Communications Staff (HFM–42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail or fax by calling the CBER Fax Information System at 1–888–223–7329.

Persons with access to Internet may obtain the document in several ways. Users of ''Web Browser'' software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators (URL's):

http://www.fda.gov/cber/cberftp.html
ftp://ftp.fda.gov/CBER/

The document may also be obtained via File Transfer Protocol (FTP). Requestors should connect to the FDA FTP Server, FTP.FDA.GOV (192.73.61.21.). The CBER documents are maintained in a subdirectory called ''CBER'' on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password. The ''READ.ME'' file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a Word Perfect 5.1 or 6.x document (*.w51,wp6), or both. Finally, the document can be obtained by ''bounce-back e-mail.'' A message should be sent to: ''CMCDNAMCA@al.cber.fda.gov''.

Submit written comments on the guidance to the Dockets Managements Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: As outlined in the President's November, 1995, National Performance Review, ''Reinventing the Regulation of Drugs Made from Biotechnology,'' FDA has announced that it will develop a single harmonized application form for all licensed biological products and all drug products. In the Federal Register of May 14, 1996 (61 FR 24227), FDA published a final rule entitled ''Elimination of the Establishment License Application for Specified Biotechnology and Specified Synthetic Biological Products.'' The final rule, also part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives, amended the biologics regulations to eliminate ELA for specified biotechnology and specified synthetic biological products, including: Therapeutic DNA plasmid products, therapeutic synthetic peptide products of 40 or fewer amino acids, monoclonal antibody products for in vivo use, and therapeutic recombinant DNA-derived products.

Prior to the publication of the final rule, the manufacturers of these biological products were required to submit both a product license application and an ELA to FDA for marketing approval (21 CFR 601.2). Under the final rule, a company may submit information in a single biologics license application for specified biotechnology and specified synthetic biological products to harmonize the approval requirements for specified biotechnology and specified synthetic biological products with similar drug products approved under the new drug provisions of the Federal Food, Drug, and Cosmetic Act (the act).

The guidance document announced in this notice is intended to provide assistance to applicants in preparing the CMC section of the harmonized application for a therapeutic

recombinant DNA-derived product or a monoclonal antibody product for in vivo use (submission to CBER) or a recombinant DNA-derived product subject to approval under section 505(b) of the act (21 U.S.C. 355(b)) (submission to CDER). The guidance document is divided into seven sections as follows: (1) Introduction; (2) Drug Substance, including discussions of description and characterization, manufacturer(s), method(s) of manufacture, process controls, reference standard, specifications/analytical methods, container/closure system, and drug substance stability; (3) Drug Product, including discussions of composition, specifications and methods for drug product ingredients, manufacturer(s), methods of manufacturing and packaging, specifications and test methods for drug product, container/closure system, microbiology, drug product stability; (4) Investigational Product/Formulation; (5) Environmental Assessment; (6) Method Validation; and (7) References.

As with other procedural guidance documents, FDA does not intend that this guidance document is all-inclusive. Alternative approaches could be warranted in specific situations, and certain aspects might not be applicable in all situations. If an applicant believed the procedures described in this guidance document were inapplicable to a specific situation for a particular product, the applicant could provide, for FDA's consideration, information supporting an alternative process. If an applicant chooses to use alternative processes, the applicant may wish to discuss the matter further with the agency to prevent expenditure of money and resources on activities that later might be determined to be unacceptable by FDA. This document does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any person, but is intended for guidance.

Interested persons may submit to Dockets Management Branch (address above) written comments on the guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and information are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 18, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–27992 Filed 10–30–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4066–N–03]

NOFA for FY 1996 Public and Indian Housing Tenant Opportunities Program; Notice of No Awards for FY 1996

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: NOFA for FY 1996 Public and Indian Housing Tenant Opportunities Program; Notice of No Awards for FY 1996.

SUMMARY: For reasons set forth in the Supplementary Information section of this document, this Notice advises the public that HUD will not award funds under the Public and Indian Housing Tenant Opportunities Program for FY 1996, until further notice.

DATES: October 31, 1996.

FOR FURTHER INFORMATION CONTACT: Priscilla S. Banks, Office of Community Relations and Involvement, Department of Housing and Urban Development, 451 Seventh Street, S.W., Room 4112, Washington, D.C. 20410; telephone: (202) 708–3611. All Indian Housing applicants may contact Tracy Outlaw, Office of Native American Programs, Department of Housing and Urban Development, 451 Seventh Street, S.W., Room B–133, Washington, D.C. 20410; telephone: (202) 755–0088. For hearing- and speech-impaired persons, these numbers may be accessed via TTY (text telephone) by calling the Federal Information Relay Service at 1–800–877–8339. (Other than the ''800'' TTY number, telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: On July 3, 1996, HUD published in the Federal Register a Notice of Funding Availability (NOFA) for FY 1996 for the Public and Indian Housing Tenant Opportunities Program Technical Assistance (FR–4066–N–01). The NOFA announced the availability of approximately $15 million to eligible resident organizations to provide technical assistance and training activities under the TOP program. These funds were appropriated for TOP from the Omnibus Rescissions and Appropriations Act of 1996.

On August 9, 1996, HUD published in the Federal Register (61 FR 41646) an amendment to the July 3, 1996, NOFA which: (1) decreased the amount of funds made available for basic and additional grants for resident organizations; (2) correspondingly increased the amount of funds made available for the provision of technical assistance by national, regional, or statewide resident organizations (NROs/RROs/SROs); and, (3) extended the eligibility and the application deadline to September 9, 1996, for NROs/RROs/SROs to apply for funding under the other requirements and criteria set out in the July 3, 1996 NOFA. The amendment also provided that NRO/RRO/SRO applicants who had previously submitted applications in accordance with the provisions in the July 3, 1996 NOFA, were permitted to amend their applications prior to the extended deadline date of September 9, 1996.

On September 20, 1996, the Congress issued a Conference Report (H. Rpt. 104–812) that accompanied H.R. 3666, the bill that appropriated funds for HUD (and other agencies) for FY 1997 and that was signed into law on September 26, 1996 (Public Law 104–204). The Conference Report stated: ''Funds for the Tenant Opportunity Program shall not be available for any purpose until the Secretary certifies that the program is working effectively. The conferees are concerned about reports of wasteful spending practices and allegedly fraudulent activities within the program, practices which put the program at risk of elimination altogether.'' (H. Rpt 104–812 at p. 59) Therefore, HUD is undertaking an evaluation of the TOP program's effectiveness and problems of concern to the Congress and will take corrective action upon confirmation of program deficiencies, in order to reduce and eliminate potential risks.

HUD will issue a NOFA for FY 1997, after incorporating program revisions that are responsive to the Conference Report regarding the need for TOP program integrity and accountability. The NOFA will include the funding appropriations from both FY 1996 and FY 1997.

Dated: October 24, 1996.

Christopher Hornig,

Deputy Assistant Secretary for Public Housing Investments.

[FR Doc. 96–27904 Filed 10–30–96; 8:45 am]

BILLING CODE 4210–33–P