

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.*  
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## 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.*  
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