III. Significance of Guidance

This draft guidance, developed under the VICH process, has been revised to conform to FDA’s good guidance practices regulation (21 CFR 10.115). For example, the document has been designated “guidance” rather than “guideline.” In addition, guidance documents must not include mandatory language such as “shall,” “must,” “require,” or “requirement,” unless FDA is using these words to describe a statutory or regulatory requirement.

The draft guidance, when finalized, will represent the Agency’s current thinking on this topic. 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 requirements of applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this draft guidance have been approved under OMB control number 0910–0032.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.


Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Rental Assistance Demonstration: Extension of Public Comment Period and Clarification of Demonstration Components

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

ACTION: Notice.

SUMMARY: On March 8, 2012, HUD published a notice in the Federal Register inviting public comments on the demonstration notice posted on HUD’s Web site entitled “Rental Assistance Demonstration—Implementation and Request for Comments” (Program Notice). This notice extends the due date for the submission of comments on the Program Notice. In addition, HUD is taking this opportunity to clarify the scope of the demonstration that took effect on March 8, 2012.

DATES: Comment Due Date: The new date for the submission of comments on the Program Notice is April 23, 2012.

Effective Date: The effective date announced in the March 8, 2012, notice is unchanged. The provisions regarding the conversion of Rent Supp and RAP properties under Section III of the Program Notice were effective on March 8, 2012. The Moderate Rehabilitation (Mod Rehab) provisions detailed in Section II of the Program Notice are not in effect until HUD reviews the public comments and issues a notice in the Federal Register.

ADDRESSES: Interested persons are invited to submit comments on applicable parts of the March 8, 2012, notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. All submissions and communications must refer to “Rental Assistance Demonstration: Notice of Web Availability and Request for Comments” docket number FR–5630–N–01. There are two methods for submitting public comments:

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at http://www.regulations.gov. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the www.regulations.gov Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule. Also, to expedite review of public comments, it is recommended commenters should organize their comments by specific topical areas and section numbers and label these areas accordingly.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–402–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service, toll-free, at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: To assure a timely response, please electronically direct requests for further information to this email address: rad@hud.gov. Written requests may also be directed to the following address: Office of Public and Indian Housing—RAD Program, Department of Housing and Urban Development, 451 7th Street SW., Room 2000; Washington, DC 20410.

SUPPLEMENTARY INFORMATION:

I. Background

On March 8, 2012, at 77 FR 14029, HUD published in the Federal Register a notice announcing HUD’s Rental Assistance Demonstration (RAD) program, which provides the
opportunity to test the conversion of public housing and other HUD-assisted properties to long-term, project-based Section 8 rental assistance to achieve certain goals, including the preservation and improvement of these properties through access by public housing agencies (PHAs) and owners to private debt and equity to address immediate and long-term capital needs; the extent to which residents have increased housing choices after the conversion; and the overall impact of conversion on the subject properties. The March 8, 2012, notice advised that HUD posted on its Web site the full details of the demonstration in a Program Notice entitled “Rental Assistance Demonstration–Partial Implementation and Request for Comments.” HUD refers the reader to the March 8, 2012, Federal Register notice for detailed information about RAD, as well as to the Program Notice, posted on HUD’s Web site at www.hud.gov/rad. This notice extends the due date for the submission of public comments on the Program Notice to April 23, 2012, and clarifies the scope of the demonstration that took effect on March 8, 2012.

II. Extension of Public Comment Due Date

The March 8, 2012, notice solicited public comment on the demonstration and established a comment due date of April 9, 2012. In order to ensure that interested members of the public have sufficient time to prepare and submit comments, HUD is extending the due date for the submission of comments on the Program Notice until April 23, 2012.

III. Clarification of Demonstration Scope

As provided in the March 8, 2012, notice and in the Program Notice, RAD consists of two components. The first component, which is covered under Sections I and II of the Program Notice for PHAs and Mod Rehab owners, respectively, allows projects funded under HUD’s public housing and Mod Rehab programs to convert to long-term Section 8 rental assistance contracts. Under this first component, PHAs and Mod Rehab owners may apply to HUD to convert to one of two forms of Section 8 Housing Assistance Payment (HAP) contracts: Project-based vouchers (PBVs) or project-based rental assistance (P BRA). The second component, which is covered under Section II of the Program Notice, for owners of Mod Rehab projects, and under Section III of the Program Notice, for owners of Rent Supplement (Rent Supp) and Rental Assistance (RAP) projects, of the Program Notice, allows projects funded under the Mod Rehab, Rent Supp and RAP programs, with a contract expiration or termination occurring after October 1, 2006, and no later than September 30, 2013, to convert tenant protection vouchers (TPVs) to PBVs.

The “Effective Date” section of the March 8, 2012, notice provided that the conversion of Rent Supp and RAP Properties under Section III of the Program Notice were effective on March 8, 2012.

The March 8, 2012, notice, at 77 FR 14030, following the explanation of the Section II and Section III provisions of the second component stated, inconsistent with the “Effective Date” provision, “These provisions are effective immediately.” Accordingly, this notice clarifies the scope of the sections of the demonstration that are effective on March 8, 2012, to eliminate any confusion made by the statement at the end of the explanation of the second component at 77 FR 14030. The only provisions that are effective immediately are, as provided in the “Effective Date” section of the notice, those of Section III of the Program Notice for the conversion of Rent Supp and RAP Properties. The Section II provisions for properties funded under Mod Rehab, which are part of the discussion of the second component, are not yet in effect.


Deborah Hernandez,
General Deputy Assistant Secretary for Public and Indian Housing.

Carol J. Galante,
Acting Assistant Secretary for Housing—Federal Housing Commissioner.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service


Multistate Conservation Grant Program; Priority List and Approval for Conservation Projects

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of receipt of priority list and approval of the projects.

SUMMARY: We, the U.S. Fish and Wildlife Service (FWS), announce the fiscal year 2012 priority list of wildlife and sport fish conservation projects from the Association of Fish and Wildlife Agencies (AFWA). As required by the Wildlife and Sport Fish Restoration Programs Improvement Act of 2000, AFWA submits a list of projects to us each year to consider for funding under the Multistate Conservation Grant program. We have reviewed the list and have awarded the grants from the list.


FOR FURTHER INFORMATION CONTACT: John C. Stremple, at the above address, or at (703) 358–2156 (phone) or john.stremple@fws.gov (email).

SUPPLEMENTARY INFORMATION: The Wildlife and Sport Fish Restoration Programs Improvement Act of 2000 (Improvement Act, Pub. L. 106–408) amended the Pittman-Robertson Wildlife Restoration Act (16 U.S.C. 669 et seq.) and the Dingell-Johnson Sport Fish Restoration Act (16 U.S.C. 777 et seq.) and established the Multistate Conservation Grant Program. The Improvement Act authorizes us to award grants of up to $3 million annually from funds available under each of the Restoration Acts, for a total of up to $6 million annually. Projects can be funded from both funds depending on the project activities. We may award grants to projects from a list of priority projects recommended to us by the Association of Fish and Wildlife Agencies. The FWS Director, exercising the authority of the Secretary of the Interior, need not fund all projects on the list, but all projects funded must be on the list.

Grantees under this program may use funds for sport fisheries and wildlife management and research projects, boating access development, hunter safety and education, aquatic education, fish and wildlife habitat improvements, and other purposes consistent with the enabling legislation.

To be eligible for funding, a project must benefit fish and/or wildlife conservation in at least 26 States, or in a majority of the States in any one FWS Region, or it must benefit a regional association of State fish and wildlife agencies. We may award grants to a State, a group of States, or one or more nongovernmental organizations. For the purpose of carrying out the National Survey of Fishing, Hunting, and Wildlife-Associated Recreation, we may award grants to the FWS, if requested by AFWA, or to a State or a group of States. Also, AFWA requires all project proposals to address its National