

The guidance announced in this notice finalizes the draft guidance dated March 2006.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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 the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 21 CFR part 601 have been approved under OMB control number 0910–0338; those in 21 CFR part 600 have been approved under OMB control number 0910–0308; and those in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (See **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5125–N–22]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, room 7266, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where

property is described as for “off-site use only” recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to John Hicks, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: **Army:** Ms. Veronica Rines, Department of the Army, Office of the Assistant Chief of Staff for Installation Management, Attn: DAIM–ZS, Rm 8536, 2511 Jefferson Davis Hwy., Arlington, VA 22202; (703)

601-2545; *Air Force*: Ms. Kathryn M. Halvorson, Director, Air Force Real Property Agency, 1700 North Moore St., Suite 2300, Arlington, VA 22209-2802; (703) 696-5502; *COE*: Ms. Tracy Beck, Army Corps of Engineers, Office of Counsel, CECC-R, 441 G Street, NW., Washington, DC 20314; (202) 761-0019; (These are not toll-free numbers).

Dated: May 24, 2007.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

**Title V, Federal Surplus Property Program
Federal Register Report for 06/01/2007 05/24/
2007**

Unsuitable Properties

Building

Florida

Bldgs. 05531, 70666

Cape Canaveral

Brevard FL 32925

Landholding Agency: Air Force

Property Number: 18200720001

Status: Unutilized

Reasons: Extensive deterioration, Secured Area, Floodway

Hawaii

Bldgs. 102, 103, 104, 105

Hickam Petro Products Storage Annex

Wheeler HI

Landholding Agency: Air Force

Property Number: 18200720002

Status: Unutilized

Reasons: Extensive deterioration

Bldgs. 106, 107, 108, 109

Hickam Petro Products Storage Annex

Wheeler HI

Landholding Agency: Air Force

Property Number: 18200720003

Status: Unutilized

Reasons: Extensive deterioration

Unsuitable Properties

Building

Hawaii

Bldg. 83111

Hickam Petro Products Storage Annex

Wheeler HI

Landholding Agency: Air Force

Property Number: 18200720004

Status: Unutilized

Reasons: Extensive deterioration

Kansas

2 Bldgs.

School Creek Boat Ramp

Junction City KS

Landholding Agency: COE

Property Number: 31200720001

Status: Excess

Reasons: Extensive deterioration

2 Bldgs.

School Creek A Loop

Junction City KS 66441

Landholding Agency: COE

Property Number: 31200720002

Status: Excess

Reasons: Extensive deterioration

Unsuitable Properties

Building

Massachusetts

Lee House

Knightville Dam Project

Huntington MA

Landholding Agency: COE

Property Number: 31200720003

Status: Unutilized

Reasons: Extensive deterioration

Former Environmental Lab

200 Coldbrook Road

Barre MA

Landholding Agency: COE

Property Number: 31200720004

Status: Unutilized

Reasons: Extensive deterioration

Missouri

Bldg. #55001

Cooper Creek

Warsaw MO 65355

Landholding Agency: COE

Property Number: 31200720005

Status: Excess

Reasons: Extensive deterioration

Unsuitable Properties

Building

New Jersey

Bldgs. 00350, 00352, 00354

Picatinny Arsenal

Morris NJ 07806

Landholding Agency: Army

Property Number: 21200720102

Status: Unutilized

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

Bldgs. 937, 1071D

Picatinny Arsenal

Morris NJ 07806

Landholding Agency: Army

Property Number: 21200720103

Status: Unutilized

Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

Bldgs. 1361, 1372

Picatinny Arsenal

Morris NJ 07806

Landholding Agency: Army

Property Number: 21200720104

Status: Unutilized

Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

Bldgs. 8339, 9014

Fort Dix

Ft. Dix NJ 08640

Landholding Agency: Army

Property Number: 21200720105

Status: Unutilized

Reasons: Extensive deterioration

Unsuitable Properties

Building

New Mexico

Bldg. 57009

Kirtland AFB

Bernalillo NM 87117

Landholding Agency: Air Force

Property Number: 18200720005

Status: Unutilized

Reasons: Secured Area, Extensive deterioration

New York

Bldgs. 21609, 22789

Fort Drum

Jefferson NY

Landholding Agency: Army

Property Number: 21200720106

Status: Unutilized

Reasons: Extensive deterioration

North Carolina

60 Vault Toilets

W. Kerr Scott Project

Wilkesboro NC 28697

Landholding Agency: COE

Property Number: 31200720006

Status: Unutilized

Reasons: Extensive deterioration

Unsuitable Properties

Building

North Dakota

Bldgs. 212, 218, 934

Grand Forks

Grand Forks ND 58205

Landholding Agency: Air Force

Property Number: 18200720006

Status: Unutilized

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

67 Duplexes, 3BR

Grand Forks AFB

Grand Forks ND 58205

Landholding Agency: Air Force

Property Number: 18200720007

Status: Unutilized

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

8 Bldgs.

Grand Forks AFB

Grand Forks ND 58205

Landholding Agency: Air Force

Property Number: 18200720008

Status: Unutilized

Directions: 1156, 1160, 1301, 1307, 1802, 1806, 1825, 1829

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

Unsuitable Properties

Building

North Dakota

Bldgs. 1158, 1159

Grand Forks AFB

Grand Forks ND 58205

Landholding Agency: Air Force

Property Number: 18200720009

Status: Unutilized

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

10 Duplexes, 4BR

Grand Forks AFB

Grand Forks ND 58205

Landholding Agency: Air Force

Property Number: 18200720010

Status: Unutilized

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

41 Duplexes, 3BR

Grand Forks AFB

Grand Forks ND 58205

Landholding Agency: Air Force

Property Number: 18200720011

Status: Unutilized

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

Bldg. 1188
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720012
Status: Unutilized

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

Unsuitable Properties

Building

North Dakota

6 Bldgs.
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720013
Status: Unutilized
Directions: 1190, 1300, 1800, 1801, 1807, 1841

Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

13—6 Vehicle Garages
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720014
Status: Unutilized

Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

Bldgs. 1202, 1212, 1216
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720015
Status: Unutilized
Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

Unsuitable Properties

Building

North Dakota

7 Bldgs.
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720016
Status: Unutilized
Directions: 1204, 1206, 1210, 1213, 1214, 1215, 1217

Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

Bldgs. 1211, 1218
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720017
Status: Unutilized
Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

7 Bldgs.
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720018
Status: Unutilized
Directions: 1302, 1304, 1308, 1331, 1333, 1335, 1337

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

Unsuitable Properties

Building

North Dakota

Bldgs. 1303, 1306
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720019
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

6 Bldgs.
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720020
Status: Unutilized
Directions: 1364, 1808, 1817, 1818, 1821, 1822

Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

14—4 Plexes, 3BR
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720021
Status: Unutilized

Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

Unsuitable Properties

Building

North Dakota

Bldgs. 1360, 1368, 1399
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720022
Status: Unutilized

Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

Bldgs. 1612, 1741
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720023
Status: Unutilized

Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

4 Bldgs.
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720024
Status: Unutilized
Directions: 1747, 1787, 1788, 1920
Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

Unsuitable Properties

Building

North Dakota

Bldgs. 1804, 1827
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720025
Status: Unutilized
Reasons: Secured Area Within 2000 ft. of flammable or explosive material

Bldgs. 1812, 1814
Grand Forks AFB

Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720026
Status: Unutilized
Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

Bldgs. 1836, 1838, 1840
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720027
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

Unsuitable Properties

Building

North Dakota

7 Bldgs.
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720028
Status: Unutilized
Directions: 1883, 1889, 1895, 1897, 1901, 1907, 1913

Reasons: Secured Area, Within 2000 ft. of flammable or explosive material

8 Duplexes, 2BR
Grand Forks AFB
Grand Forks ND 58205
Landholding Agency: Air Force
Property Number: 18200720029
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

Oklahoma

Bldg.
Sizemore Landing
Gore OK 74435
Landholding Agency: COE
Property Number: 31200720007
Status: Unutilized
Reasons: Extensive deterioration

Unsuitable Properties

Building

Oklahoma

Bldg.
Taylor Ferry
Fort Gibson OK 74434
Landholding Agency: COE
Property Number: 31200720008
Status: Unutilized
Reasons: Extensive deterioration

Pennsylvania

Bldgs. 00302, 00630, 00846
Carlisle Barracks
Cumberland PA 17013
Landholding Agency: Army
Property Number: 21200720107
Status: Unutilized
Reasons: Extensive deterioration

Texas

Bldg. 13051
Fort Hood
Bell TX 76544
Landholding Agency: Army
Property Number: 21200720108
Status: Excess
Reasons: Extensive deterioration
Bldgs. 56226, 56228

Fort Hood
Bell TX 76544
Landholding Agency: Army
Property Number: 21200720109
Status: Excess
Reasons: Extensive deterioration

Unsuitable Properties

Building

Texas

Bldgs. 56520, 56521
Fort Hood
Bell TX 76544
Landholding Agency: Army
Property Number: 21200720110
Status: Excess
Reasons: Extensive deterioration

Bldg. 4483
Fort Hood
Bell TX 76544
Landholding Agency: Army
Property Number: 21200720111
Status: Excess
Reasons: Extensive deterioration

31 Bldgs.
Texoma Lake
Denison TX
Landholding Agency: COE
Property Number: 31200720009
Status: Unutilized
Reasons: Extensive deterioration

9 Bldgs.
Texoma Lake
Denison TX
Landholding Agency: COE
Property Number: 31200720010
Status: Unutilized
Reasons: Extensive deterioration

Unsuitable Properties

Building

Texas

Summary for UNSUITABLE PROPERTIES
Total number of Properties 304

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BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Regional Habitat Conservation Plan, Williamson County, TX

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent to prepare an environmental impact statement (EIS); announcement of public scoping meeting; request for comments.

SUMMARY: We, the Fish and Wildlife Service (Service), advise the public that we intend to prepare an EIS to evaluate the impacts of, and alternatives to, the proposed issuance of an incidental take permit under the Endangered Species Act to Williamson County, Texas, and/or the Williamson County Conservation Foundation (Applicant). We also

announce a public scoping meeting and public comment period.

DATES: We must receive written comments on alternatives and issues to be addressed in the EIS by July 14, 2007. We will hold a public scoping meeting on June 14, 2007, from 5:30 p.m. to 7:30 p.m. at the Williamson County Central Maintenance Facility, 3151 S.E. Inner Loop, Georgetown, Texas 78626. The primary purpose of this meeting and public comment period is to receive suggestions and information on the scope of issues and alternatives to consider when drafting the EIS. We will accept oral and written comments at this meeting. You may also submit your comments to the address listed below. Once the draft EIS and Williamson County Regional Habitat Conservation Plan (RHCP) are completed, additional opportunity for public comment on the content of these documents and an additional public meeting will be provided.

ADDRESSES: Send written comments by mail to the Field Supervisor, at U.S. Fish and Wildlife Service, 10711 Burnet Road, Suite 200, Austin, TX 78758, or by fax at 512/490-0974.

FOR FURTHER INFORMATION CONTACT: *EIS Information:* Mr. Scott Rowin, U.S. Fish and Wildlife Service, 10711 Burnet Road, Suite 200, Austin, TX 78758; 512/490-0057 (phone); 512/490-0974 (fax); or Scott_Rowin@fws.gov (e-mail).

Williamson County RHCP

Information: Ms. Connie Watson, Public Information Officer, Williamson County Courthouse, 710 Main Street, Georgetown, TX 78626; 512/943-1663 (phone).

Other Information: You may obtain information on the purpose, membership, meeting schedules, and documents associated with the Williamson County RHCP on the Internet at <http://www.wilco.org/wccf>.

SUPPLEMENTARY INFORMATION: We intend to prepare an EIS to evaluate the impacts of, and alternatives to, the proposed issuance of an incidental take permit under the Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 1531 *et seq.*), to the Applicant. We also announce a public scoping meeting and public comment period. The Applicant proposes to apply for an incidental take permit through development and implementation of the Williamson County RHCP, as required by the Act. The Williamson County RHCP will include measures necessary to minimize and mitigate the impacts of the proposed taking of federally-listed and candidate species, and the habitats upon which they depend. We furnish this notice in compliance with the

National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), and its implementing regulations (40 CFR 1500-1508) in order to: (1) Advise other Federal and State agencies, affected tribes, and the public of our intent to prepare an EIS; (2) announce the initiation of a public scoping period; and (3) obtain suggestions and information on the scope of issues and alternatives we will consider in our EIS. We intend to gather the information necessary to determine impacts and alternatives for an EIS regarding our potential issuance of an incidental take permit to the Applicant, and the implementation of the Williamson County RHCP. The Applicant will, to the maximum extent practicable, undertake to minimize and mitigate the impacts of such incidental take of federally protected species.

Purpose and Need for Action

Section 9 of the Act prohibits "taking" of fish and wildlife species listed as endangered or threatened under Section 4, such as the Bone Cave harvestman (*Texella reyesi*), Coffin Cave mold beetle (*Batrissodes texanus*), golden-cheeked warbler (*Dendroica chrysoparia*), and black-capped vireo (*Vireo atricapilla*). The term "take" under the Act means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct. Regulations define "harm" as significant habitat modification or degradation that results in death or injury to listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). We may however under specified circumstances issue permits that allow the take of federally listed species incidental to, and not the purpose of, the carrying out of otherwise lawful activities. Regulations governing permits for endangered and threatened species are at 50 CFR 17.22 and 17.32, respectively.

Section 10(a)(1)(B) of the Act contains provisions for issuing incidental take permits to non-Federal entities for the take of endangered and threatened species, provided the following criteria are met: (1) The taking will be incidental; (2) The applicant will, to the maximum extent practicable, minimize and mitigate the impact of such taking; (3) The applicant will develop a habitat conservation plan and ensure that adequate funding for the plan will be provided; (4) The taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and