

and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities.

**DATES:** Submit written or electronic comments on the draft guidance by December 24, 2001. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms" to the Division of Compliance Information and Quality Assurance (HFC-240), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Paul J. Motise, Office of Enforcement (HFC-240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0383, e-mail: [pmotise@ora.fda.gov](mailto:pmotise@ora.fda.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms." In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a regulation providing criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper ("part 11" (21 CFR part 11)). The preamble to part 11 stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to comment on draft guidance documents. Therefore, FDA is making this draft guidance available for public comment.

The draft guidance defines terms that will be used in other FDA guidance documents about part 11. FDA believes that rather than repeat definitions in multiple guidances it would be more efficient to consolidate them in one common document. The glossary of

terms is intended to assist people who must meet part 11 requirements; it may also assist FDA staff who apply part 11 to persons subject to the regulation.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a companion draft document entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation" and is offering the opportunity to comment on it, as well. By direct reference, the companion draft document incorporates definitions contained in the draft glossary of terms.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on terms and their definitions as used in guidance documents about electronic records and electronic signatures in the context of part 11. 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. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. 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. A copy of the draft 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.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the document at [http://www.fda.gov/ora/compliance\\_ref/Part11](http://www.fda.gov/ora/compliance_ref/Part11).

Dated: August 23, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-23699 Filed 9-21-01; 8:45 am]

**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF THE INTERIOR**

##### **Fish and Wildlife Service**

##### **Notice of Intent To Prepare a Comprehensive Conservation Plan**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** We are extending the period for the submission of comments on two documents related to the Sacramento River National Wildlife Refuge. This action will provide the public with additional time to participate in the planning process of developing these documents.

**DATES:** Comments must be received by October 19, 2001.

**ADDRESSES:** Send written comments to the following address: Planning Team Leader—Sacramento River NWR, California/Nevada Refuge Planning Office, U.S. Fish and Wildlife Service, 2800 Cottage Way, W-1916, Sacramento, California, 95825. Written comments may also be sent by facsimile to (916) 414-6512.

**FOR FURTHER INFORMATION CONTACT:** Mr. Miki Fujitsubo, Planning Team Leader, (916) 414-6507.

**SUPPLEMENTARY INFORMATION:** We published a notice in June 11, 2001, **Federal Register** (66 FR 31247) announcing that the Service is preparing a Comprehensive Conservation Plan (CCP) and National Environmental Policy Act document for the Sacramento River National Wildlife Refuge. The Refuge is located in Butte, Glenn, and Tehama Counties, California. As discussed in the notice, we are preparing the CCP to comply with the National Wildlife Refuge System Administration Act of 1966. The notice stated that comments should be received by July 11, 2001. We have decided to allow the public additional time to submit comments and have extended the public comment period to October 19, 2001.

**Authority:** The authority for this action is Notice of Intent (66 FR 31247).

Dated: September 17, 2001.

**Daniel S. Walsworth,**

*Acting Manager, California/Nevada Operations Office, Region 1, U.S. Fish and Wildlife Service.*

[FR Doc. 01-23724 Filed 9-21-01; 8:45 am]

**BILLING CODE 4310-55-P**

#### **DEPARTMENT OF THE INTERIOR**

##### **Bureau of Land Management**

[UTU-78576]

##### **Recreation and Public Purposes, Classification and Termination; UT**

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** On October 4, 2000, 80 acres of public land were classified and segregated for Recreation and Public Purposes (R&PP) purposes (UTU-78576). Subsequently it was determined that a fifty acre portion of this classification contained resource values which should remain in public ownership. Therefore, the classification on these fifty acres of public land in Garfield County is being terminated. In place of this 50 acre parcel, an additional thirty acres which have been determined to not contain these values are hereby classified for disposal under the Recreation and Public Purposes Amendment Act of 1988 (Pub. L. 100-648).

**FOR FURTHER INFORMATION CONTACT:** Frank Olsen, 318 North 100 East, Kanab, UT 84741.

**SUPPLEMENTARY INFORMATION:**

Classification Termination: The description of the land on which the classification is terminated is: Salt Lake Meridian, Utah, T. 35 South, R. 5 West, Section 5, SW $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ ; Section 9, N $\frac{1}{2}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$ ; N $\frac{1}{2}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$ , containing 50 acres more or less.

Effective September 24, 2001 the Recreation and Public Purposes classification for the parcel of land described above, is hereby terminated. At 8 a.m. September 24, 2001, the land described above will be opened to the operation of the public land laws generally, including location and entry under the United States mining laws, subject to valid existing rights, other segregations of record, and the requirements of applicable law.

**New Classification:** The following public land in Garfield County, Utah has been examined and found suitable for classification for conveyance under the provisions of the R&PP Amendment Act of 1988 (Pub. L. 100-648): Salt Lake Meridian, Utah, T. 35 South, R. 5 West, Section 8, N $\frac{1}{2}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$ , NE $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$ , containing 30 acres. Garfield County intends to use the land in conjunction with the adjacent land previously classified under this Act for a public shooting range. The land is not needed for a Federal purpose. Conveyance is consistent with current Bureau of Land Management land use planning and would be in the public interest. The land is hereby segregated from appropriation under any other public land law, including locations under the mining laws.

**DATES:** On or before November 8, 2001, interested parties may submit comments regarding the proposed classification. In the absence of adverse comments, the

classification will become effective November 23, 2001.

**Rex Smart,**

*Acting Field Office Manager.*

[FR Doc. 01-23734 Filed 9-21-01; 8:45 am]

**BILLING CODE 4310--\$-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[CA-680-01-ES-4130; CACA 41804]

#### California Desert District, Notice of Realty Action, Public Use Classification; Classification of Public Lands for Recreation and Public Purposes, Serial Number Caca 41804, San Bernardino County, CA

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Realty Action CACA 41804, Classification of Public Land as Suitable for Lease/Conveyance for Recreation and Public Purposes.

**SUMMARY:** The following described public land in San Bernardino County, California has been examined and found suitable for classification for lease or conveyance to the San Bernardino County Consolidated Fire District, County Service Area (CSA) 70 under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*):

#### San Bernardino Meridian, California

T. 14N., R. 9E.

Sec. 30, W $\frac{1}{2}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ ;

Containing 5.00 acres.

The San Bernardino County Consolidated Fire District, CSA 70, a County government agency governed by the San Bernardino County Board of Supervisors, has filed an application to lease with the option for conveyance of the above described public land. The San Bernardino County Consolidated Fire District proposes to use the land for establishment of a fire station facility. The public land will be leased during the development stages. Upon substantial compliance with approved plans of development and management, the land will be conveyed.

The land is not needed for Federal purposes. Lease or conveyance under the Recreation and Public Purposes Act is in the public interest and consistent with the California Desert Conservation Area Plan, as amended. The land is located approximately 65 miles northeast of Barstow, CA, in the small unincorporated community of Baker, CA, which is situated adjacent to

Interstate 15. The site is physically suitable for the proposed use.

The terms and conditions applicable to a lease conveyance are:

A. Reservations to the United States.

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States. Act of August 30, 1890 (43 U.S.C. 945).

2. The United States will reserve all mineral deposits in the land together with the right to prospect for, mine and remove such mineral deposits under applicable laws.

B. The public land will be leased or conveyed subject to the following:

1. Those rights for construction, operation and maintenance of the 100 foot wide telegraph and telephone line granted to Pacific Telephone and Telegraph Company (now Pacific Bell), its successors or assigns, by right-of-way Serial No. CALA 0153023, pursuant to the Act of March 4, 1911, as amended (36 Stat. 1253; 43 U.S.C. 961).

Upon publication of this notice in the **Federal Register**, the public land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for lease or conveyance under the Recreation and Public Purposes Act and leasing under the mineral leasing laws.

For a period of 45 days from the date of publication of this notice, interested persons may submit comments, regarding the proposed lease/conveyance of the lands, to the Field Manager, Barstow Field Office, 2601 Barstow Road, Barstow, CA 92311, (760) 252-6023. Any adverse comments will be reviewed by the District Manager, California Desert District. In the absence of any adverse comments, this classification will become effective 60 days from the date of publication of this notice.

Dated: August 20, 2001.

**Timothy Read,**

*Barstow Field Office Manager.*

[FR Doc. 01-23737 Filed 9-21-01; 8:45 am]

**BILLING CODE 4310-40-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[MT-929-01-1420-BJ]

#### Montana: Filing of Plat of Survey

**AGENCY:** Bureau of Land Management, Montana State Office, Interior.

**ACTION:** Notice.

**SUMMARY:** The plat of the following described land is scheduled to be