

reviewed. A sponsor who submits a deficient submission should not resubmit the submission until the submission has been reviewed rigorously for accuracy and completeness.

Refusing to review deficient submissions is only part of CVM's strategy to facilitate the timely approval of safe and effective new animal drugs. CVM intends to continue issuing guidance that will clarify approval requirements and the procedures and formats for various types of submissions. CVM intends to balance the need for guidance with the need to complete pending review work. CVM encourages sponsors to request presubmission conferences to reach agreement on investigational and approval requirements for specific new animal drugs. In addition, CVM continues to encourage sponsors to submit protocols for studies that are key to approval to CVM for review well in advance of beginning the studies. Finally, CVM is committed to continuing to work to improve its processes and approve safe and effective new animal drugs in a timely manner.

This level 1 final guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on its handling of deficient submissions filed during the investigation of a new animal drug. 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 as long as it satisfies the requirements of applicable statutes and regulations.

## II. Comments

As with all of FDA's guidance, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The public will be notified of any such amendments through a notice in the **Federal Register**.

## III. Electronic Access

Persons with access to the Internet may obtain a copy of the final guidance document entitled "Guidance for Industry and Reviewers: "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During Investigation of a New Animal Drug" from the CVM home page at <http://www.fda.gov/cvm>.

Dated: August 27, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-22566 Filed 9-4-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 90D-0427]

#### **Class III Medical Devices Without Premarket Clearance; Revocation of Compliance Policy Guide 7124.30**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of a Compliance Policy Guide (CPG) entitled "Sec. 300.700 Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) (CPG 7124.30)." This CPG no longer reflects current agency policy.

**DATES:** The revocation is effective October 7, 2002.

**ADDRESSES:** Submit written requests for single copies of the CPG 7124.30 to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, FAX 301-827-0482. A copy of the CPG may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, between 9 a.m. and 4 p.m., Monday through Friday. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

**FOR FURTHER INFORMATION CONTACT:**

Jeffrey B. Governale, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(a)(1)(C)) describes a class III device, in part, as represented for use in supporting or sustaining human life, in preventing impairment of human health or presenting an unreasonable risk of illness or injury. An individual or firm that commercially distributes a class III device, in

interstate commerce, without an approved premarket approval application (PMA) or a substantially equivalent premarket notification (510(k)) is in violation of the act. In legal terms, the device is adulterated in accordance with section 501(f)(1) of the act (21 U.S.C. 351(f)(1)) and misbranded within the meaning of section 502(o) of the act (21 U.S.C. 352(o)).

On February 26, 1991, FDA issued the CPG entitled "Sec. 300.700 Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) (CPG 7124.30)." This CPG authorizes FDA's field districts to issue a Warning Letter or recommend a seizure action, if warranted, without prior concurrence and review by FDA's Center for Devices and Radiological Health (CDRH) for the referenced violations. This procedure no longer reflects current agency policy. Field districts should forward all Warning Letter and seizure recommendations concerning device premarket clearance violations to CDRH for concurrence. The Regulatory Procedures Manual includes the latter procedure.

FDA is revoking CPG 7124.30, in its entirety, to eliminate obsolete compliance policy.

## II. Electronic Access

Prior to the revocation effective date (see **DATES**), a copy of the CPG may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the CPG that may be accessed at [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgdev/cpg300-700.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg300-700.html).

Dated: August 28, 2002.

**John Marzilli,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 02-22638 Filed 9-4-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### **Single Source Cooperative Agreement Supplemental Award to the District of Columbia State Incentive Grant to Fund Best Friends Foundation Youth Development Program and "Marriage is Manly" Media Campaign**

**AGENCY:** Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services

Administration (SAMHSA), Department of Health and Human Services.

**SUMMARY:** The Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), is publishing this notice to provide information to the public concerning a planned single source cooperative agreement supplemental award in the amount of \$300,000 in FY 2002, for a project period of one year, to the District of Columbia State Incentive Grant Program, to fund Best Friends Youth Development Program and "Marriage is Manly" Media Campaign. This is not a formal request for applications. Assistance will be provided only to the District of Columbia State Incentive Grant for the sole purpose of funding the Best Friends Foundation based on the receipt of a satisfactory application that is approved by an independent review group.

**Authority/Justification:** The grant will be made under the authority of Section 509 of the Public Health Service Act 93.243, as amended. This award is being made on a single source basis because the Best Friends Foundation has a record of success and is a long-term youth-development program that encompasses a myriad of activities for youth development including advocating sexual abstinence and prevention of alcohol and drug abuse. Its work can be categorized as education, youth development, health, family development, neighborhood revitalization and welfare reform. The expansion of these activities to focus on men is appropriate as Best Friends Foundation's work with girls has been so successful. Making the award to another entity would require additional start-up time and costs, significant loss of critical information, as well as duplication of previously completed work.

The Catalog of Federal Domestic Assistance (CFDA) number for this program is 93.243.

**FOR FURTHER INFORMATION CONTACT:** Wil L. Hardy, Ph.D., M.S.W., Government Project Officer, DSCSD/SAB, Center for Substance Abuse Prevention (CSAP), SAMHSA, Room 930, Rockwall II Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-8057, [whardy@samhsa.gov](mailto:whardy@samhsa.gov).

Dated: August 29, 2002.

**Richard Kopanda,**

*Executive Officer, SAMHSA.*

[FR Doc. 02-22639 Filed 9-4-02; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[AK-962-1410-HY-P; F-14908-A; BSA-1]

#### Alaska Native Claims Selection

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

**ACTION:** Notice of decision approving lands for conveyance.

**SUMMARY:** As required by 43 CFR 2650.7(d), notice is hereby given that an appealable decision approving lands for conveyance pursuant to the Alaska Native Claims Settlement Act will be issued to Sitnasuak Native Corporation, for lands within Sec. 36, T. 11 S., R. 34 W., Kateel River Meridian, located in the vicinity of Nome, Alaska, containing approximately 0.56 acres. Notice of this decision will also be published four times in the *Nome Nugget*.

**DATES:** The time limits for filing an appeal are:

1. Any party claiming a property interest which is adversely affected by the decision, shall have until October 7, 2002, to file an appeal.

2. Parties receiving service by certified mail shall have until 30 days from the receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4, subpart E, shall be deemed to have waived their rights.

**ADDRESSES:** Copies of the decision may be obtained from: Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, # 13, Anchorage, Alaska 99513-7599.

**FOR FURTHER INFORMATION CONTACT:** Ron Royer, Land Law Examiner, (907) 271-5677.

**Ronald E. Royer,**

*Land Law Examiner, Branch of ANCSA Adjudication.*

[FR Doc. 02-22590 Filed 9-4-02; 8:45 am]

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

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[NV-030-5700-BX; Closure Notice No. NV-030-02-001]

#### Temporary Closure of Public Lands; Washoe County, NV

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

**SUMMARY:** The Carson City Field Office Manager announces the temporary closure of selected public lands under his administration. This action is being taken to provide for public safety during

the 2002 Pylon Racing Seminar and 2002 Reno National Championship Air Races.

**EFFECTIVE DATES:** September 8 through September 15, 2002.

#### FOR FURTHER INFORMATION CONTACT:

Charles P. Pope, Assistant Manager, Nonrenewable Resources, Carson City Field Office, 5665 Morgan Mill Road, Carson City, Nevada 89701. Telephone (775) 885-6000.

**SUPPLEMENTARY INFORMATION:** This closure applies to all the public, on foot or in vehicles. The public lands affected by this closure are described as follows: Mt. Diablo Meridian

T. 21 N., R. 19 E.,

Sec. 8, N $\frac{1}{2}$ NE $\frac{1}{4}$ , SE $\frac{1}{4}$ NE $\frac{1}{4}$  and E $\frac{1}{2}$ SE $\frac{1}{4}$ ;  
Sec. 16, N $\frac{1}{2}$  and SW $\frac{1}{4}$ .

Aggregating approximately 680 acres.

The above restrictions do not apply to emergency or law enforcement personnel or event officials. The authority for this closure is 43 CFR 8364.1. Persons who violate this closure order are subject to arrest and, upon conviction, may be fined not more than \$1,000 and/or imprisoned for not more than 12 months.

A map of the closed area is posted in the Carson City Field Office of the Bureau of Land Management.

Dated: June 4, 2002.

**Charles P. Pope,**

*Assistant Manager, Nonrenewable Resources, Carson City Field Office.*

[FR Doc. 02-22587 Filed 9-04-02; 8:45 am]

**BILLING CODE 4310-HC-M**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[NMMN 103474]

#### Public Land Order No. 7535; Withdrawal of National Forest System Land for the Sandia Administrative Site and the Tijeras Pueblo Interpretive Site; New Mexico

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

**ACTION:** Public land order.

**SUMMARY:** This order withdraws 14.42 acres of National Forest System land from location and entry under the United States mining laws for 20 years to protect the Sandia Administrative Site and the Tijeras Pueblo Interpretive Site.

**EFFECTIVE DATE:** September 5, 2002.

**FOR FURTHER INFORMATION CONTACT:** Sue McHenry, Cibola National Forest, 2113 Osuna Rd, NE, Suite A, Albuquerque, New Mexico 87113, 505-346-2650.