

publication in the Federal Register expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. The SIAPs contained in this amendment are based on the criteria contained in the United States Standard for Terminal Instrument Approach Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports.

The FAA has determined through testing that current non-localizer type, non-precision instrument approaches developed using the TERPS criteria can be flown by aircraft equipped with Global Positioning System (GPS) equipment. In consideration of the above, the applicable Standard Instrument Approach Procedures (SIAPs) will be altered to include "or GPS" in the title without otherwise reviewing or modifying the procedure. (Once a stand alone GPS procedure is developed, the procedure title will be altered to remove "or GPS" from these non-localizer, non-precision instrument approach procedure titles.) Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are, impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this

amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC on May 17, 1996.

Thomas C. Accardi,
Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120, 44701; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.27, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.27 NDB, NDB/DME; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * *Effective June 20, 1995*

Bartow, FL, Bartow Muni, VOR/DME or GPS RWY 9L, Amdt 1A Cancelled
Bartow, FL, Bartow Muni, VOR/DME RWY 9L, Amdt 1A
Blanding, UT, Blanding Muni, NDB or GPS RWY 35, Amdt 7 Cancelled
Blanding, UT, Blanding Muni, NDB RWY 35, Amdt 7

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Tolazoline Hydrochloride Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the

animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Lloyd, Inc. The NADA provides for intravenous use of tolazoline hydrochloride injection in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

EFFECTIVE DATE: May 23, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1616.

SUPPLEMENTARY INFORMATION: Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601, filed NADA 140-994, which provides for intravenous use of Tolazine™ Injection (each milliliter contains tolazoline hydrochloride equivalent to 100 milligrams of base activity) in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine. The drug is limited to use on or by the order of a licensed veterinarian. The NADA is approved as of April 19, 1996, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.2474 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for a 5-year period of marketing exclusivity beginning April 19, 1996, because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.2474 is added to read as follows:

§ 522.2474 Tolazoline hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains tolazoline hydrochloride equivalent to 100 milligrams of base activity.

(b) *Sponsor.* See No. 061690 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses—(i) Amount.* Administer slowly by intravenous injection 4 milligrams per kilogram of body weight or 1.8 milligrams per pound (4 milliliters per 100 kilograms or 4 milliliters per 220 pounds).

(ii) *Indications for use.* For use in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

(iii) *Limitations.* The safety of Tolazine™ has not been established in pregnant mares, lactating mares, horses intended for breeding, foals, or horses with metabolically unstable conditions. The safety of Tolazine™ has not been evaluated for reversing xylazine used as a preanesthetic to a general anesthetic. This drug is for use in horses only and not for use in food-producing animals. Users with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid accidental exposure to this product.

Accidental spillage on the skin should be washed off immediately with soap and water. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: May 15, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96-12876 Filed 5-22-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF AGRICULTURE**Forest Service****36 CFR Part 242****DEPARTMENT OF THE INTERIOR****Fish and Wildlife Service****50 CFR Part 100**

RIN 1018-AC82

Subsistence Management Regulations for Public Lands in Alaska, Subpart D; Subsistence Taking of Fish and Wildlife Regulations; Extension

AGENCY: Forest Service, USDA; Fish and Wildlife Service, Interior.

ACTION: Final rule; extension of effective date.

SUMMARY: This rule amends the Subsistence Management Regulations for Public Lands in Alaska implementing the subsistence priority for rural residents of Alaska under Title VIII of the Alaska National Interest Lands Conservation Act of 1980 by extending the effective date of 50 CFR 100.25 and 36 CFR 242.25 (Subsistence taking of wildlife) (60 FR 31542). The regulations, now set to expire on June 30, 1996, are extended through July 31, 1996, to ensure continuity of the subsistence hunting and fishing seasons until the 1996-1997 season regulations can be issued in final form.

EFFECTIVE DATE: Effective June 30, 1996, the effective date of 50 CFR 100.25 and 36 CFR 242.25 (Subsistence taking of wildlife) which were added at 60 FR 31553 is extended from July 1, 1996, through July 31, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas H. Boyd, Office of Subsistence Management, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, Alaska 99503; telephone (907) 786-3864. For questions specific to National Forest System lands, contact Ken Thompson, Regional Subsistence Manager, USDA—Forest Service, Alaska Region, P.O. Box 21628, Juneau, Alaska 99802; telephone (907) 586-7921.

SUPPLEMENTARY INFORMATION:**Background**

Title VIII of the Alaska National Interest Lands Conservation Act (ANILCA) (16 U.S.C. 3111-3126) requires that the Secretary of the Interior and the Secretary of Agriculture (Secretaries) implement a joint program to grant a preference for subsistence uses of fish and wildlife resources on public lands, unless the State of Alaska

enacts and implements laws of general applicability which are consistent with ANILCA, and which provide for the subsistence definition, preference, and participation specified in Sections 803, 804, and 805 of ANILCA. The State implemented a program that the Department of the Interior previously found to be consistent with ANILCA. However, in December 1989, the Alaska Supreme Court ruled in *McDowell v. State of Alaska* that the rural preference in the State subsistence statute violated the Alaska Constitution. The court's ruling in *McDowell* required the State to delete the rural preference from the subsistence statute, and therefore, negated State compliance with ANILCA. The Court stayed the effect of the decision until July 1, 1990.

As a result of the *McDowell* decision, the Department of the Interior and the Department of Agriculture assumed, on July 1, 1990, responsibility for implementation of Title VIII of ANILCA on public lands. On June 29, 1990, the Temporary Subsistence Management Regulations for Public Lands in Alaska were published in the Federal Register (55 FR 27114-27170). Consistent with Subparts A, B, and C of these regulations, a Federal Subsistence Board was established to administer the Federal Subsistence Management Program. The Board's composition includes a Chair appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture; the Alaska Regional Director, U.S. Fish and Wildlife Service; the Alaska Regional Director, U.S. National Park Service; the Alaska State Director, U.S. Bureau of Land Management; the Alaska Area Director, U.S. Bureau of Indian Affairs; and the Alaska Regional Forester, USDA Forest Service. Through the Board, these agencies have participated in development of regulations for Subparts A, B, and C, and the annual Subpart D regulations.

On June 15, 1995, the 1995-1996 Seasons and Bag Limits for Subsistence Management Regulations for Public Lands in Alaska were published in the Federal Register (60 FR 31542-31594). Those regulations included the section on the taking of wildlife, scheduled to expire June 30, 1996.

The Federal Subsistence Management Program initiates a process each fall with a proposed rule (60 FR 42085-42130) to provide the public with an opportunity to propose changes to the subsistence regulations. The proposals that are received are reviewed by the public and analyzed by a regional team, staff anthropologists, and biologists. The