

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

Regional Councils then meet in public forum and develop recommendations to the Federal Subsistence Board on each proposal. Because of the Federal furloughs occurring in November and later in December and January, the public review process and the proposal analysis process were delayed. This consequently resulted in scheduling delays for the Regional Council meetings and the Federal Subsistence Board meeting. As a result, implementation of the 1996–1997 Subsistence Management Regulations for Public Lands in Alaska will be delayed until August 1, 1996.

This rule effectively extends the existing regulations through July 31, 1996.

The Board finds that public notice and comment requirements under the Administrative Procedures Act (APA) for this extension are impracticable, unnecessary, and contrary to the public interest. A lapse in regulatory control after July 1 could seriously affect the continued viability of wildlife populations, adversely impact future subsistence opportunities for rural Alaskans, and would generally fail to serve the overall public interest. Therefore, the Board finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive the public notice and comment procedures prior to publication of this extension.

The Board also finds good cause for the existing rule to be extended through July 31, 1996. This July 31 date is consistent with the anticipated Regional Council and Board actions to implement the 1996–1997 Federal Subsistence Management Regulations for Public Lands in Alaska scheduled for August 1, 1996. The Board therefore finds good cause under 5 U.S.C. 553(d)(3) to make this extension effective upon publication.

Conformance with Statutory and Regulatory Authorities

National Environmental Policy Act Compliance

A Draft Environmental Impact Statement (DEIS) that described four alternatives for developing a Federal Subsistence Management Program was distributed for public comment on October 7, 1991. That document described the major issues associated with Federal subsistence management as identified through public meetings, written comments and staff analysis and examined the environmental consequences of the four alternatives. Proposed regulations (Subparts A, B, and C) that would implement the preferred alternative were included in

the DEIS as an appendix. The DEIS and the proposed administrative regulations presented a framework for an annual regulatory cycle regarding subsistence hunting and fishing regulations (Subpart D). The Final Environmental Impact Statement (FEIS) was published on February 28, 1992.

Based on the public comment received, the analysis contained in the FEIS, and the recommendations of the Federal Subsistence Board and the Department of the Interior's Subsistence Policy Group, it was the decision of the Secretary of the Interior, with the concurrence of the Secretary of Agriculture, through the U.S. Department of Agriculture-Forest Service, to implement Alternative IV as identified in the DEIS and FEIS (Record of Decision on Subsistence Management for Federal Public Lands in Alaska (ROD), signed April 6, 1992). The DEIS and the selected alternative in the FEIS defined the administrative framework of an annual regulatory cycle for subsistence hunting and fishing regulations. The final rule for Subsistence Management Regulations for Public Lands in Alaska, Subparts A, B, and C (57 FR 22940–22964) implements the Federal Subsistence Management Program and includes a framework for an annual cycle for subsistence hunting and fishing regulations.

Compliance with Section 810 of ANILCA

The intent of all Federal subsistence regulations is to accord subsistence uses of fish and wildlife on public lands a priority over the taking of fish and wildlife on such lands for other purposes, unless restriction is necessary to conserve healthy fish and wildlife populations. A Section 810 analysis was completed as part of the FEIS process. The final Section 810 analysis determination appears in the April 6, 1992, ROD which concluded that the Federal Subsistence Management Program, under Alternative IV with an annual process for setting hunting and fishing regulations, may have some local impacts on subsistence uses, but it does not appear that the program may significantly restrict subsistence uses.

Paperwork Reduction Act

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the U.S. Fish and Wildlife Service has received approval for this collection of information, with approval number 1018–0075, with the expiration date of July 31, 1996.

The collection of information will be achieved through the use of the Federal

Subsistence Hunt Permit Application. This collection information will establish whether the applicant qualifies to participate in a Federal subsistence hunt on public land in Alaska and will provide a report of harvest and location of harvest.

The likely respondents to this collection of information are rural Alaska residents who wish to participate in specific subsistence hunts on Federal land. The collected information is necessary to determine harvest success and harvest location in order to make management decisions relative to the conservation of healthy wildlife populations. The annual burden of reporting and recordkeeping is estimated to average 0.25 hours per response, including time for reviewing instructions, gathering and maintaining data, and completing and reviewing the form. The estimated number of likely respondents under the correcting amendments is less than 50, yielding a total annual reporting and recordkeeping burden of 13 hours or less.

Direct comments on the burden estimate or any other aspect of this form to: Information Collection Officer, U.S. Fish and Wildlife Service, 1849 C Street, NW., MS 224 ARLSQ, Washington, DC 20240; and the Office of Management and Budget, Paperwork Reduction Project (1018–0075), Washington, D.C. 20503. Additional information collection requirements may be imposed if Local Advisory Committees subject to the Federal Advisory Committee Act are established under subpart B. Such requirements will be submitted to OMB for approval prior to their implementation.

Economic Effects

This rule was not subject to OMB review under Executive Order 12866.

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which include small businesses, organizations or governmental jurisdictions. The Departments have determined that this rulemaking will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

This rulemaking will impose no significant costs on small entities; the exact number of businesses and the amount of trade that will result from this Federal land-related activity is unknown. The aggregate effect is an insignificant positive economic effect on a number of small entities. The number

of small entities affected is unknown; but, the fact that the positive effects will be seasonal in nature and will, in most cases, merely continue preexisting uses of public lands indicates that they will not be significant.

As of the 1990 census there are 163,000 rural Alaskans qualified to participate in subsistence hunting or fishing. Although some of the subsistence users may conduct their activities on State or private lands, it is likely that a large portion of the 163,000 rural Alaskans utilize Federal lands to some extent.

These regulations do not meet the threshold criteria of "Federalism Effects" as set forth in Executive Order 12612. Title VIII of ANILCA requires the Secretaries to administer a subsistence preference on public lands. The scope of this program is limited by definition to certain public lands. Likewise, these regulations have no significant takings implication relating to any property rights as outlined by Executive Order 12630.

The Service has determined and certifies pursuant to the Unfunded Mandates Act, 2 U.S.C. 1502 *et seq.*, that this rulemaking will not impose a cost of \$100 million or more in any given year on local or State governments or private entities.

Drafting Information

These regulations were drafted by William Knauer under the guidance of Thomas H. Boyd, Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service, Anchorage, Alaska. Additional guidance was provided by Peggy Fox, Alaska State Office, Bureau of Land Management; Sandy Rabinowitch, Alaska Regional Office, National Park Service; John Borbridge, Alaska Area Office, Bureau of Indian Affairs; and Ken Thompson, USDA—Forest Service.

List of Subjects

36 CFR Part 242

Administrative practice and procedure, Alaska, Fish, National Forests, Public Lands, Reporting and record keeping requirements, Wildlife.

50 CFR Part 100

Administrative practice and procedure, Alaska, Fish, Public Lands, Reporting and recordkeeping requirements, Subsistence, Wildlife.

Words of Issuance

For the reasons set out in the preamble, Title 36, Part 242, and Title 50, Part 100, of the Code of Federal Regulations, are amended as set forth below.

PART _____—SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA

1. The authority citation for both 36 CFR Part 242 and 50 CFR Part 100 continues to read as follows:

Authority: 16 U.S.C. 3, 472, 551, 668dd, 3101–3126; 18 U.S.C. 3551–3586; 43 U.S.C. 1733.

2. Effective June 30, 1996, the effective date for 36 CFR 242.25 and 50 CFR 100.25 which were added at 60 FR 31553 is extended from July 1, 1996 through July 31, 1996.

Dated: April 3, 1996.
Thomas H. Boyd,
Acting Chair, Federal Subsistence Board.

Dated: April 15 1996.
John C. Capp,
Acting Regional Forester, USDA—Forest Service.
[FR Doc. 96–12833 Filed 5–22–96; 8:45 am]
BILLING CODE 3410–11–M and 4310–55–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AH44

Compensation for Disability Resulting From Hospitalization, Treatment, Examination, or Vocational Rehabilitation

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

SUMMARY: This document adopts as a final rule with minor, nonsubstantive changes an interim rule amending Department of Veterans Affairs (VA) adjudication regulations concerning compensation for disability or death resulting from VA hospitalization, medical or surgical treatment, or examination. Before the interim rule, to establish entitlement to compensation for adverse results of medical or surgical treatment, the regulations required that VA be at fault or that an accident occur. In order to conform the regulations to a recent United States Supreme Court decision, the interim rule deleted the fault-or-accident requirement and instead provided that compensation is not payable for the necessary consequences of proper treatment to which the veteran consented.

EFFECTIVE DATE: This final rule is effective July 22, 1996.

FOR FURTHER INFORMATION CONTACT: Paul Trowbridge, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits

Administration, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (202) 273–7210.

SUPPLEMENTARY INFORMATION: 38 U.S.C. 1151 provides for the payment of disability or dependency and indemnity compensation for additional disability or death resulting from an injury or aggravation of an injury suffered as the result of VA hospitalization, medical or surgical treatment, examination, or pursuit of a course of vocational rehabilitation under 38 U.S.C. ch. 31. VA had long interpreted the statute to require a showing of fault on the part of VA or the occurrence of an accident to establish entitlement to § 1151 compensation for adverse consequences of VA medical treatment. This interpretation was codified at 38 CFR 3.358(c)(3).

In a recent decision, *Brown v. Gardner*, 115 S. Ct. 552 (1994), upholding a lower court decision, the U.S. Supreme Court held that the fault-or-accident requirement in former 38 CFR 3.358(c)(3) was inconsistent with the plain language of 38 U.S.C. 1151 and that no fault requirement was implicit in the statute. The Supreme Court determined that the statutory language simply requires a causal connection between an injury or aggravation of an injury and VA hospitalization, medical or surgical treatment, examination, or vocational rehabilitation, but that compensation is not payable for the necessary consequences of treatment to which a veteran consented.

In the Federal Register of March 16, 1995 (60 FR 14222), VA published an interim rule amending 38 CFR 3.358(c) in order to implement 38 U.S.C. 1151 as interpreted in that decision of the Supreme Court. Interested persons were invited to submit written comments on or before May 15, 1995. We received comments from the Paralyzed Veterans of America and from a concerned individual.

One commenter, observing that VA may provide disability examinations for beneficiaries of the British Imperial and Canadian governments and for pensioners of other nations allied with the U.S. during World War I and World War II, and that VA may conduct examinations for other Federal agencies (e.g., Office of Personnel Management, Railroad Retirement Board), asked whether VA intends to cover under 38 U.S.C. 1151 those examinees. Since the plain language of 38 U.S.C. 1151 provides for payment of benefits only for a veteran, VA has no authority to award § 1151 benefits for anyone who is not a veteran.

The same commenter suggested substituting the term "veteran" for the