FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–327 for PRIVERMECTIN (ivermectin) Drench for Sheep. The application provides for oral use of a 0.08 percent ivermectin solution in sheep for the treatment and control of various internal parasites. First Priority's PRIVERMECTIN Drench for Sheep is approved as a generic copy of Merial Limited's IVOMEC Drench for Sheep, approved under NADA 131–392. ANADA 200–327 is approved as of May 15, 2002, and the regulations are amended in § 520.1195 (21 CFR 520.1195) to reflect the approval. The basis of approval is discussed in the freedom of information summary. Section 520.1195 is also being amended to correctly describe the concentration of the product and to incorporate 21 CFR 520.1194 in a current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1194 [Removed]

2. Section 520.1194 *Ivermectin drench* is removed.

3. Section 520.1195 is revised to read as follows:

§ 520.1195 Ivermectin liquid.

(a) *Specifications*—(1) Each milliliter (mL) contains 10 milligrams (mg) ivermectin.

(2) Each mL of micellar solution contains 0.8 mg ivermectin.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 050604, 051259, 058829, and 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section.

(2) Nos. 050604 and 058829 for use of product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount*. 200 micrograms (mcg) per kilogram (/kg) of body weight as a single dose by stomach tube or as an oral drench.

(ii) *Indications for use*. For the treatment and control of large strongyles (*Strongylus equinus* (adult), *S. vulgaris* (adult and arterial larval stages), *S. endentatus* (adult and migrating tissue stages), *Triodontophorus* spp. (adult)); small strongyles, including those resistant to some benzimidazole class compounds (*Cyathostomum* spp. (adult and fourth-stage larvae), *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); pinworms (*Oxyuris equi* (adult and fourth-stage larvae)); ascarids (*Parascaris equorum* (adult and third- and fourth-stage larvae)); hairworms (*Trichostongylus axei*(adult)); large-mouth stomach worms (*Habronema muscae* (adult)); stomach bots (*Gastrophilus* spp. (oral and gastric stages)); lungworms (*Dictyocaulus arnfieldi* (adult and fourth-stage larvae)); intestinal threadworms (*Strongyloides westeri* (adult)); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

(iii) *Limitations*. Do not use in horses intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Sheep*—(i) *Amount*. 200 mcg/kg (3 mL/26 pounds) of body weight as a single dose oral drench.

(ii) *Indications for use*. For treatment and control of the adult and fourth-stage larvae of gastrointestinal roundworms (*Haemonchus contortus*, *H. placei* (adults only), *Ostertagia circumcincta*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora* (adults only), *C. curticei*, *Oesophagostomum columbianum*, *O. venulosum*(adults only), *Nematodirus battus*, *N. spathiger*, *S. papillosus* (adults only), *Chabertia ovina* (adult only), *Trichuris ovis* (adults only)); lungworms (*D. filaria*); and all larval stages of the nasal bot *Oestrus ovis*.

(iii) *Limitations*. For use in sheep only. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Do not treat sheep within 11 days of slaughter.

Dated: July 17, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–19729 Filed 8–2–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

Subsistence Management Regulations for Public Lands in Alaska, Subpart D; Seasonal Adjustments—Copper River, Afognak Bay, Southeastern Alaska Rivers

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

ACTION: Seasonal adjustments.

SUMMARY: This provides notice of the Federal Subsistence Board's in-season management actions to protect sockeye salmon escapement in Afognak Lake and in the Copper River, while still providing for a subsistence harvest opportunity. It also suspends the coho harvest regulations for three rivers in Southeastern Alaska where there are legal uncertainties and a possible conflict with an international treaty. The fishing schedules and closures will provide an exception to the Subsistence Management Regulations for Public Lands in Alaska, published in the **Federal Register** on February 7, 2002. Those regulations established seasons, harvest limits, methods, and means relating to the taking of fish and

shellfish for subsistence uses during the 2002 regulatory year.

DATES: The Afognak Bay action is effective June 13, 2002, through August 12, 2002. The second Copper River action is effective June 2, 2002, through July 31, 2002. The third Copper River action is effective June 8, 2002, through August 7, 2002. The fourth Copper River action is effective June 13, 2002, through August 12, 2002. The fifth Copper River action is effective June 20, 2002, through August 12, 2002. The sixth Copper River action is effective June 29, 2002, through August 28, 2002. The seventh Copper River action is effective July 8, 2002, through September 7, 2002. The eighth Copper River action is effective July 10, 2002, through August 31, 2002. The suspension of the coho harvest for the Stikine Taku and Alsek Rivers is effective July 10, 2002, through February 28, 2003.

FOR FURTHER INFORMATION CONTACT: Thomas H. Boyd, Office of Subsistence Management, U.S. Fish and Wildlife Service, telephone (907) 786–3888. For questions specific to National Forest System lands, contact Ken Thompson, Subsistence Program Manager, USDA—Forest Service, Alaska Region, telephone (907) 786–3592.

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 in Alaska, unless the State of Alaska enacts and implements laws of general applicability that are consistent with ANILCA and that provide for the subsistence definition, preference, and participation specified in Sections 803, 804, and 805 of ANILCA. In December 1989, the Alaska Supreme Court ruled that the rural preference in the State subsistence statute violated the Alaska Constitution and, therefore, negated State compliance with ANILCA.

The Department of the Interior and the Department of Agriculture (Departments) assumed, on July 1, 1990, responsibility for implementation of Title VIII of ANILCA on public lands. The Departments administer Title VIII through regulations at Title 50, Part 100 and Title 36, Part 242 of the Code of Federal Regulations (CFR). Consistent with Subparts A, B, and C of these regulations, as revised January 8, 1999, (64 FR 1276), the Departments established a Federal Subsistence Board 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, National Park Service; the Alaska State Director, Bureau of Land Management; the Alaska Regional Director, Bureau of Indian Affairs; and the Alaska Regional Forester, USDA Forest Service. Through the Board, these agencies participate in the development of regulations for Subparts A, B, and C, which establish the program structure and determine which Alaska residents are eligible to take specific species for subsistence uses, and the annual Subpart D regulations, which establish seasons, harvest limits, and methods and means for subsistence take of species in specific areas. Subpart D regulations for the 2002 fishing seasons, harvest limits, and methods and means were published on February 7, 2002, (67 FR 5890). Because this rule relates to public lands managed by an agency or agencies in both the Departments of Agriculture and the Interior, identical closures and adjustments would apply to 36 CFR part 242 and 50 CFR part 100.

The Alaska Department of Fish and Game (ADF&G), under the direction of the Alaska Board of Fisheries (BOF), manages sport, commercial, personal use, and State subsistence harvest on all lands and waters throughout Alaska. However, on Federal lands and waters, the Federal Subsistence Board implements a subsistence priority for rural residents as provided by Title VIII of ANILCA. In providing this priority, the Board may, when necessary, preempt State harvest regulations for fish or wildlife on Federal lands and waters.

These adjustments (including restricted subsistence fishing schedules) are necessary because of predictions of potentially weak returns of chinook, summer-run chum, and fall-run chum salmon in the Yukon River drainage, poor runs of chinook and chum salmon in the Kuskokwim River drainage, and the need to manage the sockeye salmon run in the Chitina Subdistrict of the Copper River based on in-season run assessments. These actions are authorized and in accordance with 50 CFR 100.19(d)–(e) and 36 CFR 242.19(d)–(e).

Afognak Bay

The 2002 return of sockeye salmon to the Afognak River drainage is one of the lowest observed since 1986. Current weir counts and run timing allow managers to project that the total escapement may be substantially below the minimum escapement goal of 40,000 fish. In response to this poor return at this time, the Alaska Department of Fish and Game (ADF&G) has closed the State sport, commercial, and subsistence fisheries targeting sockeye salmon within Afognak Bay waters. After consultation with subsistence users and ADF&G managers, closure of the Federal subsistence seine and gill net fishery for salmon within the Afognak Bay waters of the Alaska Maritime National Wildlife Refuge is the responsible course of action as all remaining sockeye salmon entering Afognak Bay are required to achieve spawning escapement goals. Subsistence fishing with rod and reel for all species except sockeye salmon continues to be permitted. This closure action is taken to ensure the conservation of the Afognak River sockeye salmon stock.

Copper River—Chitina Subdistrict

In December 2001, the Board adopted regulatory proposals establishing a new Federal subsistence fishery in the Chitina Subdistrict of the Copper River. This fishery is open to Federally qualified users having customary and traditional use of salmon in this Subdistrict. The State also conducts a subsistence fishery in this Subdistrict that is open to all Alaska residents.

Management of the fishery is based on the numbers of salmon returning to the Copper River. A larger than predicted salmon run will allow additional fishing time. A smaller than predicted run will require restrictions to achieve upriver passage and spawning escapement goals. A run that approximates the pre-season forecast will allow fishing to proceed similar to the pre-season schedule with some adjustments made to fishing time based on in-season data. Adjustments to the preseason schedule are expected as a normal function of an abundance-based management strategy. State and Federal managers, reviewing and discussing all available in-season information, will make these adjustments.

While Federal and State regulations currently differ for this Subdistrict, the Board indicated that Federal in-season management actions regarding fishing periods were expected to mirror State actions for the 2002 season. The State established a preseason schedule of allowable fishing periods based on daily projected sonar estimates. This preseason schedule is intended to distribute the harvest throughout the salmon run and provide salmon for

upriver subsistence fisheries and the spawning escapement. State and Federal subsistence fisheries in this Subdistrict close simultaneously by regulation on September 30, 2002. No deviation from this date is anticipated.

Special Actions 2—8, adopted the changing State preseason schedule for the Federal subsistence fishery, adjusting the weekly or daily harvest period to protect the sockeye salmon run or to provide additional harvest opportunity as more fish entered the river. Each Special Action superseded the previous one. Continuous fishing with no additional adjustments is presently anticipated until the regularly scheduled end of the season (September 30, 2002.)

Southeastern Alaska Rivers

In December 2001, the Federal Subsistence Board adopted a proposal that established regulations for the taking of coho salmon throughout Southeast Alaska including on the Stikine, Taku and Alsek Rivers. The salmon resources on these three transboundary rivers are managed under the auspices of the Pacific Salmon Treaty (PST), an agreement for management of salmon stocks that are harvested by both the United States and Canada. The most recent agreement (the 1999 PST Revised Annexes) negotiated by the Pacific Salmon Commission, the administrative and management authority of the PST, has been interpreted as prohibiting the establishment of new fisheries until abundance based management plans are developed. There are legal uncertainties regarding the exact relationship of Title VIII of ANILCA to the PST and whether these fisheries are a matter of domestic allocation or constitute new fisheries. Action by the Federal Subsistence Board in December 2001 to establish a subsistence fishery in the transboundary rivers may violate the principles in Annex IV, Chapter 1 of the PST. The Board, therefore, acted to suspend the harvest for the remainder of the regulatory year for that portion of the requirements (50 CFR 100.27(i)(13)(vi) and 36 CFR 242.27(i)(13)(vi)) that allows a subsistence coho salmon fishery within the three transboundary rivers. The Board will continue to work within established international protocols through the PSC and the Transboundary Panel to provide future subsistence fisheries in these three transboundary rivers.

The Board finds that additional public notice and comment requirements under the Administrative Procedure Act (APA) for these emergency closures are impracticable, unnecessary, and contrary to the public interest. Lack of appropriate and immediate conservation measures could seriously affect the continued viability of fish 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)(3)(B) to waive additional public notice and comment procedures prior to implementation of these actions and pursuant to 5 U.S.C. 553(d)(3) to make this rule effective as indicated in the **DATES** section.

Conformance With Statutory and Regulatory Authorities

National Environmental Policy Act Compliance

A Final Environmental Impact Statement (FEIS) was published on February 28, 1992, and a Record of Decision on Subsistence Management for Federal Public Lands in Alaska (ROD) was signed April 6, 1992. The final rule for Subsistence Management Regulations for Public Lands in Alaska, Subparts A, B, and C (57 FR 22940–22964, published May 29, 1992) implemented the Federal Subsistence Management Program and included a framework for an annual cycle for subsistence hunting and fishing regulations. A final rule that redefined the jurisdiction of the Federal Subsistence Management Program to include waters subject to the subsistence priority was published on January 8, 1999, (64 FR 1276.)

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 appeared 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 the program is not likely to significantly restrict subsistence uses.

Paperwork Reduction Act

The adjustment and emergency closures do not contain information collection requirements subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995.

Other Requirements

The adjustments have been exempted from 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 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 economic effect (both positive and negative) on a small number of small entities supporting subsistence activities, such as boat, fishing gear, and gasoline dealers. The number of small entities affected is unknown; but, the effects will be seasonally and geographically-limited in nature and will likely not be significant. The Departments certify that the adjustments will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act. Under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*), this rule is not a major rule. It does not have an effect on the economy of $100 million or more, will not cause a major increase in costs or prices for consumers, and does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

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, the adjustments have no potential takings of private property implications as defined by Executive Order 12630.

The Service has determined and certifies pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that the adjustments will not impose a cost of $100 million or more in any given year on local or State governments or private entities. The implementation is by Federal agencies, and no cost is involved to any State or local entities or Tribal governments.

The Service has determined that the adjustments meet the applicable standards provided in Sections 3(a) and 3(b)(2) of Executive Order 12988, regarding civil justice reform.

In accordance with Executive Order 13132, the adjustments do not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. Title VIII of ANILCA precludes the State from exercising management authority over fish and wildlife resources on Federal lands. Cooperative salmon run assessment efforts with ADF&G will continue.

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and 512 DM 2, we have evaluated possible effects on Federally recognized Indian tribes and have determined that there are no effects. The Bureau of Indian Affairs is a participating agency in this rulemaking.

On May 18, 2001, the President issued Executive Order 13211 on regulations that significantly affect energy supply, distribution, or use. This Executive Order requires agencies to prepare Statements of Energy Effects when undertaking certain actions. As these actions are not expected to significantly affect energy supply, distribution, or use, they are not significant energy actions and no Statement of Energy Effects is required.

Drafting Information

William Knauer drafted this document under the guidance of Thomas H. Boyd, of the Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service, Anchorage, Alaska. Taylor Brelsford, Alaska State Office, Bureau of Land Management; Rod Simmons, Alaska Regional Office, U.S. Fish and Wildlife Service; Bob Gerhard, Alaska Regional Office, National Park Service; Ida Hildebrand, Alaska Regional Office, Bureau of Indian Affairs; and Ken Thompson, USDA-Forest Service, provided additional guidance.

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

Dated: July 16, 2002.

Kenneth E. Thompson,

Subsistence Program Leader, USDA-Forest Service.

Dated: July 17, 2002.

Thomas H. Boyd,

Acting Chair, Federal Subsistence Board.

[FR Doc. 02–19620 Filed 8–2–02; 8:45 am]

BILLING CODE 3410–11–P; 4310–55–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[OH1521; FRL72553]

Completeness Status of Oxides of Nitrogen Regulations; Submission of a Complete Plan by the State of Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; completeness determination.

SUMMARY: EPA is notifying the public that it has made a finding that Ohio's July 11, 2002 submission regarding State Implementation Plan (SIP) revisions for the reduction of oxides of nitrogen (NO_X) is a complete submission under the Clean Air Act. Ohio's SIP revision was submitted to satisfy EPA's October 27, 1998 regulation entitled, ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone,'' otherwise known as the ''NO_X SIP Call''. The NO_X SIP Call originally required 22 states and the District of Columbia to submit enforceable SIP measures to control NO_X emissions. The intended effect of a NO_X SIP revision is to reduce emissions of NO_X in order to help attain the national ambient air quality standard for ozone.

On December 26, 2000, EPA determined that Ohio, along with several other states, had failed to submit a SIP in response to the NO_X SIP Call, thus starting an 18-month clock for the mandatory imposition of sanctions and the obligation for EPA to promulgate a Federal Implementation Plan (FIP) within 24 months. On July 11, 2002, Ohio submitted a NO_X SIP and EPA has determined that Ohio's SIP submission is complete. Therefore, through this rule, EPA is notifying the public that the sanctions clock as it pertains to Ohio is terminated.

This determination is limited to the completeness of Ohio's submission and is not an approval of Ohio's plan. A determination as to the adequacy of Ohio's plan will be made at a later date and only after a thorough review of Ohio's submission by EPA personnel and the completion of rule and comment rulemaking.

EFFECTIVE DATE: August 5, 2002.

FOR FURTHER INFORMATION CONTACT: John Paskevicz, Engineer, Regulation Development Section, Air Programs Branch, Air and Radiation Division (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604, Telephone: (312) 886–6084. Copies of documents relative to this action are available at the above listed contact for inspection during normal business hours. The interested persons wanting to examine these documents should make an appointment at least 24 hours before the visiting day.

SUPPLEMENTARY INFORMATION:

The contents of this rule are listed in the following outline:

I. Background
A. What Criteria are Used to Judge the Submission Complete?
B. What is the Next Step?
II. What Action is EPA Taking Today?
III. Administrative Requirements

I. Background

Throughout this document, whenever ''we,'' ''us'' or ''our'' is used, we mean EPA.

This rule is simply an announcement that the NO_X SIP revision submitted by Ohio to EPA on July 11, 2002 has been found to be complete. NO_X control plans are required from certain states, including Ohio, as a result of EPA's NO_X SIP Call that found that certain upwind states were significantly contributing to ozone transport and preventing east coast states from attaining the ambient ozone air quality standard (63 FR 57356, October 27, 1998). Sources within states affected by this finding are large emitters of NO_X which, using available technology, can control NO_X emissions. These large emitters include coal fired electric generating units (EGUs) and industrial boilers (non-EGUs).

EPA's SIP Call established emission budgets, for all of the listed states (including the District of Columbia). Listed states are required to demonstrate in their NO_X plans that they can meet the EPA specified NO_X emissions budget. A major feature of the plans are allowance trading programs which states, including Ohio, have included to provide flexibility for sources to meet the strict emission reduction requirements of a state plan.

After a series of court challenges, the deadline by which most of the 22 states and the District of Columbia were required to submit NO_X SIP revisions was extended to October 30, 2000. *See* 65 FR 81366, December 26, 2000 (discussion of legal history surrounding EPA's NO_X SIP Call). Several states, including the State of Ohio, failed to submit NO_X plans by the October 2000 deadline. As a result, EPA published a finding of this failure in the **Federal Register** on December 26, 2000 (65 FR 81366). This finding triggered, among