

the Bureau of Veterinary Medicine is amending the existing regulation to list the approval of the supplemental application. However, this newly codified approval, as well as the underlying approval, remain subject to any future actions brought under the provisions of 21 CFR 558.15.

A freedom of information summary has not been prepared because 21 CFR 514.11 does not require such a summary under the circumstances of this codification.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(iii) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.145 is amended by revising paragraph (b) to read as follows:

§ 558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.

(b) *Approvals.* (1) Premix level of 20 grams of chlortetracycline per pound, 4.4 percent of sulfamethazine, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound has been granted; for sponsor see Nos. 000196 and 010042 in § 510.600(c) of this chapter.

(2) Premix level of 40 grams of chlortetracycline per pound, 8.8 percent of sulfamethazine, and procaine penicillin equivalent in activity to 20 grams of penicillin per pound has been granted; for sponsor see No. 010042 in § 510.600(c) of this chapter.

Effective date. September 10, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: September 1, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82-24539 Filed 9-9-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed for United Suppliers, Inc., providing for safe and effective use of a 0.4-gram-per-pound tylosin premix for making complete swine feeds.

EFFECTIVE DATE: September 10, 1982.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-128), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: United Suppliers, Inc., P.O. Box 538, Eldora, IA 50627, is the sponsor of supplemental NADA 102-590 submitted on its behalf by Elanco Products Co. This supplement provides for use of premixes containing 0.4 gram of tylosin (as tylosin phosphate) per pound for making complete swine feeds. The firm currently holds approval for use of the 0.8- and 10-gram-per-pound tylosin premixes for making swine feeds. Both feeds are used for increased rate of weight gain and improved feed efficiency.

Approval of this NADA is based on safety and effectiveness data contained in Elanco's approved NADA 12-491. Elanco has authorized use of the data in NADA 12-491 to support approval of this application. This approval does not change the approved use of the drug. Consequently, approval of the NADA poses no increased human risk from exposure to residues of the animal drug, nor does it change the conditions of the drug's safe use in the target animal species.

Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this is a Category II supplemental approval which does not require reevaluation of the safety and effectiveness data in NADA 12-491.

The supplement is approved and the regulations are amended accordingly.

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, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.625 is amended by revising paragraph (b)(46) to read as follows:

§ 558.625 Tylosin.

(b) * * *

(46) To 017475: 0.4, 0.8, and 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.

Effective date. September 10, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: September 1, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82-24536 Filed 9-9-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid Sodium, Roxarsone, and Bacitracin Methylene Disalicylate

AGENCY: Food and Drug Administration.

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 Hoffmann-La Roche, Inc., providing for use of lasalocid sodium combined with roxarsone and bacitracin methylene disalicylate (bacitracin MD) in broiler chicken feeds for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in reduction of lesions due to *E. tenella*; and for increased rate of weight gain.

EFFECTIVE DATE: September 10, 1982.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-147), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110, filed an NADA (131-894) providing for use of broiler chicken feeds containing lasalocid sodium with roxarsone and bacitracin MD for prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in reduction of lesions due to *E. tenella*; and for increased rate of weight gain.

This approval is based in part on Hoffmann-La Roche's approved NADA 96-298 which demonstrates the safety and effectiveness of lasalocid sodium when used for prevention of coccidiosis in finished chicken feed. Approval is also based on approved NADA 102-485 which demonstrates that addition of roxarsone at a concentration of 45.4 grams per ton (g/ton) to feeds containing lasalocid sodium (68 to 113 g/ton) aids in reducing lesions due to *Eimeria tenella*. In addition, A. L. Laboratories' NADA 46-592 demonstrates that bacitracin MD is safe and effective for increased rate of weight gain and improved feed efficiency in chickens to 8 weeks of age. NADA 131-894 further

demonstrates that addition of bacitracin MD at 10 to 25 g/ton to the combination of lasalocid sodium and roxarsone does not interfere with their safety or effectiveness, or with animal safety and effectiveness of bacitracin MD, in the 3-way combination, for increasing the rate of weight gain in broiler chickens. Drug residue depletion studies demonstrate that simultaneous presence of the three drugs in tissue samples does not interfere with their individual assays. The residue depletion studies also reveal that after the 5-day withdrawal period of the combination product: (1) Roxarsone residues are well below tolerance levels specified in 21 CFR 556.60 (0.5 part per million (ppm) in uncooked muscle tissue and 2 ppm in uncooked, edible byproducts), (2) lasalocid residues are below the tolerance specified in 21 CFR 556.347 (0.05 ppm for total residues in edible tissues), and (3) no microbiologically active residues of bacitracin MD are detected at zero withdrawal using a method of assay with a detection limit to 0.5 ppm. The NADA is approved and the regulations are amended to reflect the approval.

Approval of this NADA poses no increased human risk from exposure to residues of the animal drugs, nor does it change the conditions of the drugs' safe use in the target animal species. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this NADA has been treated as a Category II supplemental NADA and does not require reevaluation of the human safety data for lasalocid, roxarsone, or bacitracin MD.

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, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended as follows:

1. In § 558.76 by revising paragraph (e)(3)(viii) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

(e) * * *

(3) * * *

(viii) Lasalocid sodium alone or with roxarsone as in § 558.311.

2. In § 558.311 by adding a third 3-way combination consisting of lasalocid sodium, roxarsone, and bacitracin methylene disalicylate to the table in paragraph (e)(2) to read as follows:

§ 558.311 Lasalocid sodium.

(e) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(2) * * *	Roxarsone 45.4 plus bacitracin 10 to 25.	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain.	For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 017210 and 011801 in § 510.600(c) of this chapter, bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	000004

3. In § 558.530 by adding new paragraph (f)(4) to read as follows:

§ 558.530 Roxarsone.

(f) * * *

(4) *Additional combinations.*

Roxarsone may be used in combination "as an aid in the reduction of lesions due to *E. tenella*" as follows:

- (i) Lasalocid as in § 558.311.
- (ii) Lasalocid plus bacitracin methylene disalicylate as in § 558.311.
- (iii) Lasalocid plus lincomycin as in § 558.311.

Effective date, September 10, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: September 2, 1982.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 82-24888 Filed 9-9-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 606, 610, and 640

[Docket No. 79N-0316]

Source Plasma (Human); Dating Period and Reduction of Record Retention Requirements

Correction

In FR Doc. 82-19179, appearing at page 30968, in the issue of Friday, July 16, 1982, make the following correction:

On page 30969, in the second column, the List of Subjects, the first entry should read "21 CFR Part 606".

BILLING CODE 1505-01-M

21 CFR Part 880

[Docket No. 78N-1271]

Classification of Neonatal Ventilatory Effort Monitors (Apnea Detectors); Revocation of Final Rule

AGENCY: Food and Drug Administration.

ACTION: Revocation of final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its final rule of October 21, 1980, that classified neonatal ventilatory effort monitors (apnea detectors) into class II (performance standards). The agency has determined that this device is part of another device, breathing frequency monitors, which the agency has classified into class II as part of the proceeding to classify anesthesiology devices. Because the two regulations concern the same generic type of device, the agency is revoking the final rule of October 21, 1980. The administrative record for the final rule shall be

included with the administrative record for the final regulation classifying breathing frequency monitors into class II.

DATES: Effective September 10, 1982; comments by October 12, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David S. Shindell, Bureau of Medical Devices (HFK-430), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: In a final rule in the Federal Register of October 21, 1980 (45 FR 69684), FDA classified neonatal ventilatory effort monitors (apnea detectors) into class II (performance standards). This action was taken as part of the agency's overall implementation of the Medical Device Amendments of 1976 (the amendments) that established a system for the regulation of medical devices for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I (general controls), class II (performance standards), and class III (premarket approval). The amendments also established a procedure for the agency to promulgate regulations classifying each generic type of device into one of these three classes. Because the same generic type of device may be used in different medical speciality areas (anesthesiology, neurology, general and plastic surgery, etc.) under different names, the agency continues to consolidate its list of generic types of devices.

After publication of the final rule to classify neonatal ventilatory effort monitors (apnea detectors) as part of the general hospital and personal use device classification proceeding, the agency determined that neonatal ventilatory effort monitors (apnea detectors) are essentially the same as another generic type of device, breathing frequency monitors, that had been proposed for classification into class II as part of the classification proceeding for anesthesiology devices. The proposed regulation to classify breathing frequency monitors into class II was published in the Federal Register of November 2, 1979 (44 FR 63340). No comments were received on either

regulation. In a final rule published in the Federal Register of July 16, 1982 (47 FR 31130), FDA classified into class II breathing frequency monitors (21 CFR 868.2375). To avoid unnecessary device classification regulations, the agency is revoking the October 21, 1980 final rule classifying neonatal ventilatory effort monitors (apnea detectors). The administrative record for the October 21, 1980 final rule shall be included in the administrative record (Docket No. 78N-1698) for the proceeding to classify breathing frequency monitors.

The agency has determined for reasons set forth above that notice and public procedure and delayed effective date are unnecessary, impractical, and contrary to public interest. However, interested persons may by October 12, 1982, submit to the Dockets Management Branch (HFA-305) (address above), written comments on this revocation. The comments will determine whether this final rule should be modified.

Persons who disagree with the final classification of a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

List of Subjects in 21 CFR Part 880

General hospital and personal use devices, Medical devices.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

§ 880.2440 [Removed]

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 880 is amended by removing § 880.2440 *Neonatal ventilatory effort monitor (apnea detector)*.

Effective date: September 10, 1982.

Dated: September 3, 1982.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-24887 Filed 9-9-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 168

Grazing Regulations for Former Navajo-Hopi Joint Use Area Lands

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Interim Rule with Public Comment Period.

SUMMARY: The Bureau of Indian Affairs is promulgating interim regulations governing grazing and conservation measures for rangeland in the Hopi portion of the former Navajo-Hopi joint use area. (An addition to these regulations for the Navajo portion of the joint use area will be published at a later date.) These regulations are promulgated pursuant to a judgment issued May 4, 1982, in the case of *Hopi Tribe v. Watt*, Civ. No. 81-272 PCT-EHC, U.S.D.C. D. Ariz., and are effective upon publication in the *Federal Register*. In order to continue the consultation process with the Hopi Tribe, and provide for public input pending final rulemaking, interested parties shall have 30 days to submit comments on these regulations.

DATES: Effective September 10, 1982. Comments on this interim rule must be submitted on or before October 11, 1982.

ADDRESSES: Send comments to Bureau of Indian Affairs, Division of Water and Land Resources, 1951 Constitution Ave., N.W., Washington, D.C. 20245.

FOR FURTHER INFORMATION CONTACT: Sam Miller, Bureau of Indian Affairs, Division of Water and Land Resources, 1951 Constitution Ave., N.W., Washington, D.C. 20245, telephone number (202) 343-4004.

SUPPLEMENTARY INFORMATION: These regulations are a result of the longstanding dispute between the Hopi and Navajo Tribes over the so-called joint use area created by the Executive Order of December 16, 1982. The court in *Healing v. Jones*, 210 F. Supp. 125 (1962) determined that while the Hopi Tribe held an area within the Executive Order boundaries for their exclusive use and occupancy, the remaining area was shared in common and each tribe had a right to use the land. Although the Navajos were using the joint use area to the almost total exclusion of the Hopis, the court found that it had no authority to take remedial action. In response to this situation, Congress enacted the Navajo-Hopi Settlement Act, Pub. L. 93-531, 88 Stat. 1713, in 1974 which provided, inter alia, for the partition of the joint use area between the two tribes. The Act was amended by Pub. L. 96-305, 94 Stat. 929, in 1980. The amended act is now codified as 25 U.S.C. 640d et seq.

In litigation over the conflicting interpretations of the amended act, *Hopi Tribe v. Watt*, supra, the court determined in a May 4, 1982 judgment that Part 153 of 25 CFR (redesignated Part 168 on March 30, 1982, 47 FR 13326)

was invalid because it did not have the concurrence of the Hopi Tribe. The court ordered the Secretary to prepare new regulations and obtain Hopi tribal concurrence with them, within 60 days. Regulations were prepared but the Secretary was unable to secure the Hopi Tribe's concurrence. On August 31, the court instructed the Secretary to issue regulations within 10 days. In an effort to reconcile the court's August 31 instructions with the May 4 judgment, the Department is issuing these interim regulations while at the same time soliciting public comments and attempting to secure Hopi tribal concurrence prior to issuance of a final rule.

It has been determined that this interim rule is not a major rule as that term is defined in Executive Order 12291 of February 17, 1981, 46 FR 13193, because it will have a limited economic impact on a small number of people. For the same reason, it has been determined that this final rule would not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, Pub. L. 96-354.

The information collection requirement contained in § 168.6 has been approved by the Office of Management and Budget under 44 U.S.C. 3507 and assigned clearance number 1076-0027.

This interim rule is being made effective upon publication in the *Federal Register* under the exception in 5 U.S.C. 553(d)(3), which permits rules to become effective in less than 30 days for good cause found and published with the rule. The regulations need to be in effect upon publication in order to meet court ordered deadlines and to allow the Secretary to fulfill his responsibilities under the Navajo-Hopi Settlement Act.

List of Subjects in 25 CFR Part 168

Grazing lands, Indian lands, Livestock.

Accordingly, 25 CFR Part 168 is revised as follows:

PART 168—GRAZING REGULATIONS FOR THE HOPI PARTITIONED LANDS AREA

- Sec.
- 168.1 Definitions.
 - 168.2 Authority.
 - 168.3 Purpose.
 - 168.4 Establishment of range units.
 - 168.5 Grazing capacity.
 - 168.6 Grazing on range units authorized by permit.
 - 168.7 Kind of livestock.
 - 168.8 Grazing fees.
 - 168.9 Assignment, modification and cancellation of permits.

- Sec.
- 168.10 Conservation and land use provisions.
 - 168.11 Range improvements; ownership; new construction.
 - 168.12 Special permit requirements and provisions.
 - 168.13 Fences.
 - 168.14 Livestock trespass.
 - 168.15 Control of livestock diseases and parasites.
 - 168.16 Impoundment and disposal of unauthorized livestock.
 - 168.17 Concurrence procedures.
 - 168.18 Appeals.
 - 168.19 Information collection.
- Authority: 5 U.S.C. 301; 25 U.S.C. 2, 640d-8, and 640d-18.

§ 168.1 Definitions

As used in this Part, terms shall have the meanings set forth in this section.

(a) "Secretary" means the Secretary of Interior or his designee;

(b) "Area Director" means the officer in charge of the Phoenix Bureau of Indian Affairs Area Office (or his successor; and/or his authorized representative) to whom has been delegated the authority of the Assistant Secretary—Indian Affairs to act in all matters pertaining to lands partitioned to the Hopi Tribe under its jurisdiction, within the boundaries of the former Joint Use Area.

(c) "Superintendent" means the Superintendent, Hopi Agency or his designee.

(d) "Tribal Government" means the Hopi Tribal Council, or its duly designated representative.

(e) "Project Officer" means the former Special Project Officer of the Bureau of Indian Affairs, Administrative Office, Flagstaff, Arizona 86001, who had been delegated the authority of the Commissioner of Indian Affairs to act in matters respecting the former Joint Use Area.

(f) "Former Joint Use Area" means the area established by the United States District Court for the District of Arizona in the case entitled *Healing v. Jones*, 210 F. Supp. 125 (1962), which is inside the Executive Order area (Executive Order of December 16, 1882) but outside Land Management District 6 and which was partitioned by the judgment of partition dated April 18, 1979.

(g) "Hopi Partition Area" means that portion of the Former Joint Use Area which has been added to the Hopi Tribe's reservation.

(h) "Range Unit" means a tract of range land designated as a management unit for administration of grazing.

(i) "Range improvements" means fences, stockwater devices, corrals, trails and other similar devices or practices which are applied to the land

to enhance range productivity or usability.

(j) "permit" means a revocable privilege granted in writing limited to entering on and utilizing forage by domestic livestock on a specified tract of land. The term as used herein shall include written authorizations issued to enable the crossing or trailing of domestic livestock across specified tracts or range units.

(k) "Interim permit" means a permit granted to members of the Navajo tribe residing on Hopi Partitioned Lands who meet the qualifications of § 168.6(b) in accordance with Pub. L. 93-531 as amended.

(l) "Animal unit" (AU) means one adult cow with unweaned calf by her side or equivalent thereof based on comparative forage consumption. Accepted conversion factors are: sheep and goats, one ewe, doe, buck or ram equals 0.25 A.U.; one sheep unit year long (SUYL) equals 0.25 Animal Unit year long; horses and mules, one horse, mule, donkey or burro equals 1.25 A.U.

(m) "Tribe" means the Hopi Tribe including all villages and clans.

(n) "Allocate" means to apportion grazing, including the determination of who may graze livestock, the number and kind of livestock, and the place such livestock will be grazed.

(o) "Person awaiting relocation" means a resident of the Hopi Partitioned Area who meets each of the following criteria: (1) Is listed on the Bureau of Indian Affairs enumeration (as defined in (q) below); (2) has a livestock inventory listed with the project Officer (see (r) below); (3) is awaiting relocation under the Settlement Act; and (4) was grazing livestock on the date of the entry of the Judgment of Partition, April 18, 1979.

(p) "Carrying capacity" means the maximum stocking rate possible without inducing damage to vegetation or related resources.

(q) "BIA enumeration" means the list of persons living on and improvements located within the former Joint Use Area obtained by interviews by the Project Officer's staff.

(r) "Livestock inventory" means the original list as amended (developed by the Project Officer in 1976-77) of livestock owned by persons having customary grazing use in the former Joint Use Area.

(s) "Settlement Act" means the Act of December 22, 1974, 88 Stat. 1712, as amended.

(t) "Life Tenant" means a person who has applied for and been granted a life estate lease pursuant to Section 30 of the Settlement Act, 25 U.S.C. 640d-28.

§ 168.2 Authority.

It is within the general authority of the Secretary to protect Indian trust lands against waste and to prescribe rules and regulations under which these lands may be leased or permitted for grazing. Also, under the Navajo-Hopi Settlement Act as amended, 25 U.S.C. 640d-8 and 18, the Secretary is authorized and directed to: (a) Reduce livestock grazing within the former Joint Use Area to carrying capacity, (b) restore the grazing range potential of the resource to maximum grazing extent feasible, (c) survey, monument and fence the partition boundary, (d) protect the rights and property of individuals awaiting relocation or authorized to reside on life estates, and (e) to administer conservation practices, including grazing control and range restoration activities on the Hopi Partitioned Lands.

§ 168.3 Purpose.

These regulations are issued to implement the Secretary's responsibilities mandated by the Settlement Act and subsequent U.S. District Court Judgment filed May 4, 1982, in the case, *Hopi Tribe v. Watt*, Civ. No. 81-272 PCT-EHC. This portion of the regulations apply only to lands partitioned to the Hopi Tribe within the former Joint Use Area.

§ 168.4 Establishment of range units.

The Area Director will use Soil and Range Inventory data to establish range units on the Hopi Partitioned Area to provide for a surface land management program to restore the land to its full grazing potential and maintain that potential to the maximum extent feasible. The establishment of range units on Hopi Partitioned Lands is subject to the concurrence of the Hopi Tribe in accordance with § 168.17 of these regulations.

§ 168.5 Grazing capacity.

(a) The Area Director shall prescribe the maximum number of each kind of livestock which may be grazed on land under his jurisdiction without inducing damage to vegetation or related resources on each range unit and the season or seasons of use to achieve the objectives of the land recovery program required by the Settlement Act.

(b) The Area Director shall review the stocking rate upon which the grazing permits are issued on a continuing basis and adjust that rate as conditions warrant.

§ 168.6 Grazing on range units authorized by permit.

Grazing use on range units is authorized only by permits granted under paragraph (a) or (b) below.

(a) Grazing permits to Hopi tribal members on their partitioned lands. The Area Director shall assign grazing privileges to the Hopi Tribe for lands within Hopi Partitioned Lands. The tribal government will then allocate use to their tribal members for permit periods not to exceed five years. Grazing use by Hopi tribal enterprises may be authorized. The Area Director will issue permits based on the determination of the Hopi tribal government.

(b) Interim Grazing Permit for persons awaiting relocation. Navajo Tribal members who have maintained both a permanent residence on Hopi Partitioned lands; a livestock inventory since enumeration; and meet all the criteria listed in § 168.1(o), shall be eligible for an interim grazing allocation on Hopi Partitioned lands under the following terms and conditions:

(1) The Area Director shall first verify that an applicant meets the criteria of the definition in § 168.1(o) and will issue all permits.

(2) The permitted number shall not exceed either (i) 10 SUYL (See § 168.1(1)) for each eligible family member, or (ii) the grazing applicant's livestock inventory reduced by voluntary sales as adjusted by reproduction, in accordance with procedures developed by the Project Officer based upon the study by Stubblefield and Camfield, 1975 page 5. The determination of the person to whom permits will be issued and the number of livestock to be permitted will be based on information provided by the permit applicant and an assessment of the number of dependents residing in the immediate household.

(3) The permit shall authorize grazing for a specific number and kind of animal(s) in a specified range unit. Interim grazing permits will not be issued in excess of one-half the authorized carrying capacity of the Hopi Partition area.

(4) Subject to the provisions of § 168.9(b), permits shall expire when the person awaiting relocation is relocated pursuant to the Settlement Act. No interim permit will be issued for a term greater than one year. Permits may be reissued upon application and redetermination of eligibility. All interim permits will expire at the end of the period provided by the Settlement Act for the completion of relocation, 25 U.S.C. 640d-13(e). When a Navajo permit holder discontinues grazing livestock or reduces the number being grazed whether by reason of his relocating or for any other reason, his grazing permit will be cancelled or

reduced and no permit will be issued in lieu thereof. The total number of authorized animal units grazed by the Navajo permit holders awaiting relocation will be reduced by the number of animal units authorized under the cancelled or reduced permit.

§ 168.7 Kind of livestock.

Unless determined otherwise by the Area Director for conservation purposes, the Hopi Tribe may determine, subject to the authorized carrying capacity, the kind of livestock that may be grazed by their tribal members on the range units within the Hopi Partitioned Land area.

§ 168.8 Grazing fees.

(a) The rental value of all uses of Hopi Partitioned lands by persons who are not members of the Hopi Tribe, including eligible holders of interim permits, will be determined, and assessed by the Area Director and paid in accordance with 25 USC 640d-15.

(b) The Hopi Tribe has established an annual grazing fee to be assessed all range users on Hopi Partitioned lands. The annual Hopi grazing fee shall be paid in full in advance of the annual effective date of the permit, prior to the issuance of a grazing permit. Payment shall be made to the Superintendent, Hopi Agency, for disbursement to the Hopi tribal treasurer. Failure of the permittee to make payment in full in advance will be cause to deny issuance of the grazing permit.

§ 168.9 Assignment, modification and cancellation of permits.

(a) Grazing permits to Hopi tribal members shall not be reassigned, subpermitted or transferred without the approval of the permit issuer(s).

(b) The Area Director may revoke or withdraw all or any part of any grazing permit in Hopi Partitioned lands by cancellation or modification on 30 days written notice of a violation of the permit or special conditions affecting the land or the safety of the livestock thereon, as may result from flood, disaster, drought, contagious diseases, etc. Except in the case of extreme necessity, cancellation or modification shall be effected on the next annual anniversary date of the grazing permit following the date of notice. Revocation or withdrawal of all or any of the grazing permit by cancellation or modification as provided herein is effective on the date the notice of cancellation or modification is received and shall be appealable under 25 CFR Part 2.

§ 168.10 Conservation and land use provisions.

Grazing operations shall be conducted in accordance with recognized principles of good range management. Conservation management plans necessary to accomplish this will be made a part of the grazing permit by stipulation.

§ 168.11 Range improvements; ownership; new construction.

Except as provided by the Relocation Act, range improvements placed on the permitted land shall be considered affixed to the land unless specifically excepted therefrom under the permit terms. Written permission to construct or remove improvements must be obtained from the Hopi Tribe.

§ 168.12 Special permit requirements and provisions.

All grazing permits shall contain the following provisions:

(a) Because the lands covered by the permit are in trust status, all of the permittees' obligations on the permit and the obligations of his sureties are to the United States as well as to the beneficial owners of the lands.

(b) The permittee agrees he will not use, cause, or allow to be used any part of the permitted area for any unlawful conduct or purpose.

(c) The permit authorizes only the grazing of livestock.

§ 168.13 Fences.

Fencing will be erected by the Federal Government around the perimeter of the 1882 Executive Order Area, Land Management District 6, and on the boundary of the former Joint Use Area partitioned to each tribe by the Judgment of Partition of April 18, 1979. Fencing of other areas in the former Joint Use Area will be required for a range recovery program in accordance with the range units established under § 168.4. Such fencing shall be erected at Government expense and ownership shall be clearly identified by appropriate posting on the fencing. Intentional destruction of Federal property will be treated as a violation of 18 U.S.C. 1164.

§ 168.14 Livestock trespass.

The owner of any livestock grazing in trespass on the Hopi Partitioned Lands Area is liable to a civil penalty of \$1 per head per day for each animal in trespass, together with the replacement value of the forage consumed and a reasonable value for damages to property injured or destroyed. The Superintendent may take appropriate action to collect all such penalties and damages and seek injunctive relief when appropriate. All payments for such

penalties and damages shall be credited to the Tribe. The following acts are prohibited:

(a) The grazing upon or driving across any of the Hopi Partitioned Lands of any livestock without an approved grazing or crossing permit;

(b) Allowing livestock to drift and graze on lands without an approved permit;

(c) The grazing of livestock upon lands within an area closed to grazing of that class of livestock;

(d) The grazing of livestock by permittees upon any land withdrawn from use for grazing purpose to protect it from damage, after the receipt of notice from the Area Director; and

(e) Grazing livestock in excess of those numbers and kinds authorized on a livestock grazing permit approved by the Area Director.

§ 168.15 Control of livestock diseases and parasites.

Whenever livestock within the Hopi Partitioned Lands become infected with contagious or infectious diseases or parasites or have been exposed thereto, such livestock must be treated and the movement thereof restricted in accordance with applicable laws.

§ 168.16 Impoundment and disposal of unauthorized livestock.

Unauthorized livestock within any range unit of the Hopi Partitioned Lands which are not removed therefrom within the periods prescribed by the regulation will be impounded and disposed of by the Superintendent as provided herein.

(a) When the Area Director determines that unauthorized livestock use is occurring and has definite knowledge of the kind of unauthorized livestock, and knows the name and address of the owners, such livestock may be impounded any time five days after written notice of intent to impound unauthorized livestock is mailed by certified mail or personally delivered to such owners or their agent.

(b) When the Area Director determines that unauthorized livestock use is occurring but does not have complete knowledge of the number and class of livestock or if the name and address of the owner thereof are unknown, such livestock will be impounded anytime 15 days after the date of a General Notice of Intent to Impound unauthorized livestock is first published in the local newspaper, posted at the nearest chapter house, and in one or more local trading posts.

(c) Unauthorized livestock on the Hopi Partitioned Lands which are owned by persons given notice under

paragraph (a) of this section, and any unauthorized livestock in areas for which a notice has been posted and published under paragraph (b) of this section, will be impounded without further notice anytime within the twelve-month period immediately following the effective date of the notice.

(d) Following the impoundment of unauthorized livestock a notice of sale of impounded livestock will be published in the local newspaper, posted at the nearest chapter house, and in one or more local trading posts. The notice will describe the livestock and specify the date, time and place of sale. The date set shall be at least 5 days after the publication and posting of such notice.

(e) The owners or their agent may redeem the livestock anytime before the time set for the sale by submitting proof of ownership and paying for all expenses incurred in gathering, impounding and feeding or pasturing the livestock and any trespass fees and/or damages caused by the animals.

(f) Livestock erroneously impounded shall be returned to the rightful owner and all expenses accruing thereto shall be waived.

(g) If the livestock are not redeemed before the time fixed for their sale, they shall be sold at public sale to the highest bidder, provided his bid is at or above the minimum amount set by the Superintendent based upon U.S.D.A.'s current Agricultural Statistic's Report for Arizona. If a bid at or above the minimum is not received the livestock may be sold at private sale at or above the minimum amount, reoffered at public sale, condemned and destroyed, or otherwise disposed of. When livestock are sold pursuant to this regulation, the superintendent shall furnish the buyer a bill of sale or other written instrument evidencing the sale.

(h) The proceeds of any sale of impounded livestock shall be applied as follows: (1) To the payment of all expenses incurred by the United States in gathering, impounding, and feeding or pasturing the livestock; (2) in payment of any penalties or damages assessed pursuant to § 168.14 of this part which penalties or damages shall be credited to the Hopi tribe as provided in said section; (3) any remaining amount shall be paid over to the owner of said livestock upon his submitting proof of ownership. Any proceeds remaining after payment of the first and second items noted above not claimed with one year from the date of sale, will be credited to the Hopi Tribe.

§ 168.17 Concurrence procedures.

(a) Definitions: As used in this section, terms shall have the meaning set forth as follows:

(1) "Concurrence" means agreement by the Area Director and the Hopi Tribe, speaking through the Chairman of the Tribe (or his designee).

(2) "Non-concurrence" means disagreement between the Area Director and the Hopi Tribe, speaking through the Chairman of the Hopi Tribe (or his designee), or a failure of the Hopi Tribe to respond to a proposal by the Area Director in a timely manner.

(3) "Timely manner" means a period of thirty days, unless this period is shortened by the existence of an emergency. Upon request by the Tribal Council, the Area Director may extend the 30 day period. In instances where this period applies to the Area Director, he may extend the period by so notifying the Tribe.

(4) "An emergency" is a condition that the Area Director finds threatens the rights and property of life tenants and persons awaiting relocation or one that the Area Director finds is causing the condition of the range land to deteriorate.

(5) "Conservation practice" is a program consisting of a series of acts in conformance with the Bureau's range management policies and procedures which maintains or seeks to achieve the grazing potential of range lands on a continuing basis.

(6) "Range restoration activities" is a program consisting of a series of range management acts, including but not limited to procedures which increase range forage production, reduce erosion, improve range usability and reduce stocking by issuing grazing permits to persons residing on Hopi partitioned lands at rates which maximize the carrying capacity of the range lands on a continuing basis.

(7) "Grazing control" is a program consisting of a series of range management acts, including but not limited to procedures by which grazing permits are issued to persons residing on Hopi partitioned lands, which limit the grazing on range lands to its carrying capacity.

(b) The Area Director will seek the participation of the Hopi Tribe in his investigation, formulation and planning of conservation practices for Hopi partitioned lands. The Area Director will submit, in writing, the proposed plan to the Hopi Tribe.

(c) Upon receipt of the Area Director's proposed conservation practices, the Hopi Tribe will deliver, in writing, to the Area Director its concurrence or non-

concurrence on all of the proposed conservation practices in a timely manner. The Area Director will continue to seek Hopi Tribal participation during the review process.

(d) Concurrence of the Hopi Tribe will be sought on all conservation practices, range restoration activities, and grazing control programs on the Hopi Partitioned Lands.

(1) If the Area Director and the Hopi Tribe concur on all or part of the proposed conservation practices in writing in a timely manner, those practices concurred upon may be immediately implemented.

(2) If the Hopi Tribe does not concur on all or part of the proposed conservation practices in a timely manner, the Area Director will submit in writing to the Hopi Tribe a declaration of non-concurrence. The Area Director will then notify the Hopi Tribe in writing of a formal hearing to be held not sooner than 15 days from the date of the non-concurrence declaration.

(i) The formal hearing on non-concurrence will permit the submission of written evidence and argument concerning the proposal. Minutes of the hearing will be taken. Following the hearing, the Area Director may amend, alter or otherwise change his proposed conservation practices. Except as provided in § 168.17d(1) above, if following the hearing, the Area Director altered or amends portions of his proposed plan of action, he will submit those individual altered or amended portions of the plan to the Tribe in a timely manner for their concurrence.

(ii) In the event The Tribe fails or refuses to give its concurrence to the proposal at the hearing, then the implementation of such proposal may only be undertaken in those situations where the Area Director expressly determines in a written order, based upon findings of fact, that the proposed action is necessary to protect the rights and property of life tenants and/or persons awaiting relocation.

§ 168.18 Appeals.

Appeals from decisions issued under this part will be in accordance with procedures in 25 CFR Part 2.

§ 168.19 Information Collection.

The information collection requirement(s) contained in this regulation have been approved by the Office of Management and Budget under 44 U.S.C. 3501 et seq. and assigned clearance number 1076-0027. The information is being collected in order to ascertain eligibility for the issuance of a

grazing permit. Response is mandatory in order to obtain a permit.

Kenneth Smith,

Assistant Secretary, Indian Affairs.

September 8, 1982.

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Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

Removal of One of the Conditions of Approval of the West Virginia Permanent Program Under the Surface Mining Control and Reclamation Act of 1977

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: This document amends 30 CFR Part 948 by removing one of the conditions of approval (condition (a)(8)(iii)) of the West Virginia permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). West Virginia has submitted provisions to the Office of Surface Mining (OSM) which satisfy the condition.

After providing opportunity for public comment and conducting a thorough review of the program amendment, the Secretary of the Interior has determined that the modification to the West Virginia program satisfies condition (a)(8)(iii) by amending section E.03 a. of its regulations to require that water leaving the permit area will meet all applicable Federal and State water quality standards for the river, stream or drainway into which it is discharged. Accordingly, the Secretary of the Interior has removed condition (a)(8)(iii) from the approval of the West Virginia program.

Part 948 of 30 CFR Chapter VII is being amended to implement this decision.

EFFECTIVE DATE: The removal of the condition of the approval is effective September 10, 1982.

FOR FURTHER INFORMATION CONTACT: Arthur W. Abbs, Chief, Division of State Program Assistance, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, South Building, 1951 Constitution Avenue, N.W., Washington, D.C. 20240, Telephone: (202) 343-5351.

SUPPLEMENTARY INFORMATION:

Background

On March 3, 1980, the Secretary of the Interior received a proposed regulatory program from the State of West Virginia. On January 21, 1981, following a review of that proposed program as outlined in 30 CFR Part 732, the Secretary of the Interior approved the program conditioned on the correction of minor deficiencies. Information pertinent to the general background of the permanent program submission, as well as the Secretary's findings, the disposition of comments and explanations of the conditions of approval of the West Virginia program can be found in the January 21, 1981 *Federal Register* (46 FR 5915-5956).

On April 29, 1981, the State provided a copy of proposed coal refuse disposal regulations to OSM for review (Administrative Record No. WV 400). On June 8, 1981, OSM provided an informal listing of deficiencies found in the proposed regulations (Administrative Record No. WV 401a) and informed the State that the promulgated regulations must be submitted as a program amendment which would be subject to public comment. The regulations were promulgated by West Virginia on October 1, 1981, and submitted as a program amendment on October 29, 1981.

The Director, OSM, determined that the amendment contained minor deficiencies and therefore, conditionally approved the amended regulations on May 11, 1982 (47 FR 20119-20122, Administrative Record No. WV 438). Finding 4 of the Director's approval stated that the State regulations required that water leaving the permit area would not lower the water quality of the river, stream or drainway into which it is discharged. Since this conflicts with the requirements of 30 CFR 816.41 and 817.41, the Director conditioned the approval of the amended regulations upon compliance with the Federal requirements by June 15, 1982 (See Condition (a)(8)(iii)).

On June 17, 1982, the State of West Virginia submitted a copy of an amendment to the Coal Refuse Regulations to satisfy Condition (a)(8)(iii) of the conditional approval (Administrative Record No. WV 442). The amendment was filed on an emergency basis with the West Virginia Secretary of State on June 17, 1982. A *Federal Register* notice announcing receipt and a public comment period on the proposed amendment was published July 9, 1982 (47 FR 29852-29853). The comment period closed on August 9,

1982. Public disclosure of comments by Federal agencies was made on August 17, 1982, in the *Federal Register* (47 FR 35783, 8-17-82).

Secretary's Findings

Pursuant to 30 CFR 732.17 the Secretary finds the program amendment to section E.03 a. of the West Virginia regulations submitted on June 17, 1982, corrects condition (a)(8)(iii) of the approval of the program. The amended regulation clearly requires that water leaving the permit area will meet all applicable Federal and State water quality standards for the river, stream or drainway into which it is discharged and is therefore no less effective than 30 CFR 816.41 and 817.41.

Public comments

The West Virginia Surface Mining and Reclamation Association stated that the revised regulation was contradictory to Chapter 20, Article 6, Section 12(f) of the Code of West Virginia. The Association further stated that the original regulation had been written in such a manner as to be in conformance with State law.

Although 20-6-12(f) does contain provisions relating to water quality, the regulation in question is intended to implement the requirements of Section 20-6-13(b)(10)(B) of the West Virginia Surface Coal Mining and Reclamation Act. This section requires compliance set by applicable requirements of the State law. Therefore, the revised regulation is consistent with the State's surface mining act. In addition, the regulation is consistent with Section 10C.03c of the conditionally approved regulations of January 21, 1982. Please refer to finding 13.7 of the Secretary's approval of January 21, 1982, for additional discussion (46 FR 5919, January 21, 1981, Administrative Record Number WV 392).

Utah International had two comments concerning the revised regulation. The first comment concerned differences in the requirements of the Surface Mining Control and Reclamation Act and the Clean Water Act. Since this comment does not relate to the revised regulation, it will not be addressed.

The second comment concerned the use of sediment ponds to comply with the requirements of Section 515(b)(10)(B)(i) of SMCRA (and corresponding Section 20-6-13(b)(10)(B) of the West Virginia Surface Coal Mining and Reclamation Act). Utah International stated that Section 515 of SMCRA required prevention of additional contributions of suspended solids only. The use of sediment ponds would intercept natural sediment as