

Dated: April 23, 2001.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 558

Animal Drugs, Feeds, and Related Products; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to reflect changes to previously approved new animal drug applications (NADAs). Several sponsors currently listed as sponsors of approved applications and specified in the animal drug approval regulations are incorrect. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective May 3, 2001.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567.

SUPPLEMENTARY INFORMATION: FDA has found several errors in the agency's regulations concerning approval of animal drugs, feeds, and related products including the list of sponsors of approved applications. To correct those errors, FDA is amending 21 CFR 510.600(c)(1) and (c)(2) to remove 28 sponsor names and their corresponding drug labeler codes (DLCs) because the firms are no longer the holders of any approved NADAs. This document is also amending the animal drug approval regulations by correcting nonsubstantive DLC errors in 21 CFR 522.2120, 558.274, 558.625, and 558.630.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

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 the

congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

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 parts 510, 522, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entries for "Albion Laboratories, Inc.", "Balfour Guthrie & Co.", "Diamond Shamrock Corp.", "DuPont Merck Pharmaceutical Co.", "Farmers Feed & Supply Co.", "Franklin Laboratories, Inc.", "Gland-O-Lac Co.", "Michael Gordon, Inc.", "Henwood Feed Additives", "Heska Corp.", "Hubbard Milling Co.", "Lemmon Co.", "Mattox & Moore, Inc.", "McClellan Laboratories, Inc.", "Nixon and Co.", "Osborn Laboratories, Inc.", "Peter Hand Foundation", "Premier Malt Products, Inc.", "Protein Blenders, Inc.", "The Rath Packing Co.", "Rhone Merieux Canada, Inc.", "Shell Chemical Co.", "Square Deal Fortification Co.", "Sterling Winthrop, Inc.", "Syntex Animal Health, Inc.", "V.P.O., Inc.", "Vet-A-Mix, Inc.", and "Westchester Veterinary Products, Inc.", and in the table in paragraph (c)(2) by removing the entries for "000033, 000056, 000693, 000934, 010290, 010290, 011461, 011485, 011789, 012190, 012487, 025001 026186, 027863, 028260, 032707, 033999, 036108, 043728, 043729, 043732, 043735, 043737, 043738, 043743, 043744, 047015, 049047, and 063604".

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.2120 [Amended]

4. Section 522.2120 *Spectinomycin dihydrochloride injection* is amended in paragraph (b) by removing "Nos. 000033 and 059130" and adding in its place "No. 059130".

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

5. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.274 [Amended]

6. Section 558.274 *Hygromycin B* is amended by removing and reserving paragraph (a)(5); by removing "011790 and" in paragraph (a)(7); and by removing "026186," from the "Sponsor" column in the table in paragraphs (c)(1)(i) and (c)(1)(ii).

§ 558.625 [Amended]

7. Section 558.625 *Tylosin* is amended by removing and reserving paragraphs (b)(16), (b)(19), and (b)(34), and in paragraph (b)(79) by removing "012286" and adding in its place "017519".

§ 558.630 [Amended]

8. Section 558.630 *Tylosin and sulfamethazine* is amended in paragraph (b)(8) by removing ", 026186".

Dated: April 23, 2001.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 11

RIN 1076-AE15

Law and Order on Indian Reservations

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Temporary final rule and request for comments.

SUMMARY: The Bureau of Indian Affairs (BIA) is amending its regulations contained in 25 CFR Part 11 to add the

Santa Fe Indian School property (Southwest Region, New Mexico) to the listing of courts of Indian offenses. This amendment will establish a Court of Indian Offenses for a period not to exceed one year. It is necessary to establish a Court of Indian Offenses with jurisdiction over the Santa Fe Indian School property in order to protect lives and property.

DATES: Effective Date: This rule is effective on May 3, 2001 and expires on May 1, 2002.

Comments Date: Comments must be received on or before July 2, 2001.

ADDRESSES: Send comments on this rule to Ralph Gonzales, Office of Tribal Services, Bureau of Indian Affairs, 1849 C Street NW., MS 4660, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Iris A. Drew, Tribal Government Officer, Southwest Regional Office, Bureau of Indian Affairs, 615 First Street NW., Albuquerque, NM 87125-6567, at (505) 346-7592; or Ralph Gonzales, Branch of Judicial Services, Office of Tribal Services, Bureau of Indian Affairs, 1849 C Street NW., MS 4660 Washington, DC 20240, at (202) 208-4401.

SUPPLEMENTARY INFORMATION: The authority to issue this rule is vested in the Secretary of the Interior by 5 U.S.C. 301 and 25 U.S.C. 2 and 9; and 25 U.S.C. 13, which authorizes appropriations for "Indian judges." See *Tillett v. Hodel*, 730 F.Supp. 381 (W.D. Okla. 1990), aff'd 931 F.2d 636 (10th Cir. 1991) *United States v. Clapox*, 13 Sawy. 349, 35 F. 575 (D.Ore. 1888). This rule is published in exercise of the rulemaking authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs.

On December 27, 2000, Congress passed the Omnibus Indian Advancement Act of 2000, Public Law 106-568, 114 Stat. 2868. Section 823(a) of that Act places the Santa Fe Indian School property and the Indian Hospital in "trust for the benefit of the 19 Pueblos of New Mexico," which establishes federal Indian criminal jurisdiction over the Santa Fe Indian School and Indian Hospital grounds to wit:

In general—The land described in this subsection is the tract of land, located in the city and county of Santa Fe, New Mexico, upon which the Santa Fe Indian School is located and more particularly described as all that certain real property, excluding the tracts described in paragraph (2), as shown in the United States General Land Office Plat of the United States Indian School Tract dated March 19, 1937, and recorded at Book 363, Page 024, Office of the Clerk, Santa Fe County, New Mexico, containing a total acreage of 131.43 acres, more or less.

(2) Exclusions—The excluded tracts described in this paragraph are all portions of any tracts heretofore conveyed by the deeds recorded in the Office of the Clerk, Santa Fe County, New Mexico, at—

- (A) Book 114, Page 106, containing 0.518 acres, more or less;
- (B) Book 122, Page 45, containing 0.238 acres, more or less;
- (C) Book 123, Page 228, containing 14.95, more or less; and
- (D) Book 130, Page 84, containing 0.227 acres, more or less,

leaving, as the net acreage to be included in the land described in paragraph (1) and taken into trust pursuant to subsection (a), a tract containing 115.5 acres, more or less.

Limitations and Conditions—The land taken into trust pursuant to subsection (a) shall remain subject to—

- (1) Any existing encumbrances, rights of way, restrictions, or easements of record;

(2) The right of the Indian Health Service to continue use and occupancy of 10.23 acres of such land which are currently occupied by the Santa Fe Indian Hospital and its parking facilities as more fully described as Parcel "A" in legal description No. Pd-K-51-06-01 and recorded as Document No. 059-3-778, Bureau of Indian Affairs Land Title & Records Office, Albuquerque, New Mexico; and

(3) The right of the United States to use, without cost, additional portions of land transferred pursuant to this section, which are contiguous to the land described in paragraph (2), for purposes of the Indian Health Service.

Id. at §§ 823(b)–(c).

A provisional Court of Indian Offenses must be established for the Santa Fe Indian School and Indian Hospital to protect the lives, persons, and property of people residing at and attending or visiting the school and hospital, until the 19 Pueblos establish a tribal court or otherwise request a CFR Court to exercise criminal jurisdiction. This court shall function for a period not to exceed one year. Judges of the Court of Indian Offenses shall be authorized to exercise all the authority provided under 25 CFR part 11 including: Subpart D—Criminal Offenses; Subpart H—Appellate Proceedings; Subpart J—Juvenile Offender Procedure; issuance of arrest and search warrants pursuant to 25 CFR 11.302 and 11.305 and the Indian Law Enforcement Reform Act, 25 U.S.C. 2803(2) (1998). BIA officials had already begun to set up a provisional Court of Indian Offenses pursuant to 25 CFR 11.100(a) for the Southwest Region to address this law enforcement need. This final rule is intended to establish a provisional Court of Indian Offenses. This court will not be exercising the following authority under 25 CFR part 11: Subpart E—Civil Actions; Subpart F—Domestic Relations; Subpart G—

Probate Proceedings; Subpart I—Children's Court; and Subpart K—Minor-in-Need-of-Care Procedure.

Determination To Issue a Final Rule

The Department has determined that the public notice and comment provisions of the Administrative Procedure Act, 5 U.S.C. 553(b), do not apply because of the good cause exception under 5 U.S.C. 553(b)(3)(B), which allows the agency to suspend the notice and public procedure when the agency finds for good cause that those requirements are impractical, unnecessary and contrary to the public interest. This amendment will establish a provisional Court of Indian Offenses for the Santa Fe Indian School property and Indian Hospital, New Mexico, that was placed in trust for the benefit of the 19 Pueblos. If this provisional court is not established, there is a potential risk to public safety and a further risk of significant financial liability to the Federal Government from a lawsuit for failure to execute diligently its trust responsibility and provide adequate law enforcement on trust land. Delaying this rule to solicit public comment through the proposed rulemaking process would thus be contrary to the public interest.

Determination To Make Rule Effective Immediately

We are making the rule effective on the date of publication in the **Federal Register** as allowed under the good cause exception in 5 USC 553(d)(3). Delaying the effective date of this rule is unnecessary and contrary to the public interest because there is a critical need to expedite establishment of this Court of Indian Offenses. There is now a void in law enforcement at the Santa Fe Indian School and Indian Hospital and an increase in visitors to the grounds of these facilities is imminent. For these reasons, an immediate effective date is in the public interest and in the interest of the Pueblos. Accordingly, this amendment is issued as a final rule effective immediately.

We invite comments on any aspect of this rule and we will revise the rule if comments warrant. Send comments on this rule to the address in the **ADDRESSES** section.

Regulatory Planning and Review (Executive Order 12866)

In accordance with the criteria in Executive Order 12866, this rule is not a significant regulatory action. OMB makes the final determination under Executive Order 12866.

- a. This rule will not have an annual economic effect of \$100 million or adversely affect an economic sector,

productivity, jobs, the environment, or other units of government. A cost-benefit and economic analysis is not required. The establishment of this Court of Indian Offenses is estimated to cost less than \$200,000 annually to operate. The cost associated with the operation of this court will be shared among the Office of Indian Education, the Bureau of Indian Affairs, and Indian Health Service.

b. This rule will not create inconsistencies with other agencies' actions. The Department of the Interior through the Bureau of Indian Affairs has the sole responsibility and authority to establish Courts of Indian Offenses on Indian reservations.

c. This rule will not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. The establishment of this Court of Indian Offenses will not affect any program rights of the nineteen Pueblos. Its primary function will be to administer justice for misdemeanor offenses within the Santa Fe Indian School grounds. The court's jurisdiction will be limited to criminal offense provided in 25 CFR part 11.

d. This rule will not raise novel legal or policy issues. The Solicitor analyzed and upheld the Department of the Interior's authority to establish Courts of Indian Offenses in a memorandum dated February 28, 1935. The Solicitor found that authority to rest principally in the statutes placing supervision of the Indians in the Secretary of the Interior, 25 U.S.C. 2 and 9, and 25 U.S.C. 13, which authorizes appropriations for "Indian judges." The United States Supreme Court recognized the authority of the Secretary to promulgate regulations with respect to Courts of Indian Offenses in *United States v. Clapox*, 35 F. 575 (D.Ore. 1888).

Regulatory Flexibility Act

The Department of the Interior, BIA, certifies that this rule will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). An initial Regulatory Flexibility Analysis is not required. Accordingly, a Small Entity Compliance Guide is not required. The amendment to 25 CFR part 11.100(a) will establish a Court of Indian Offences with limited criminal jurisdiction over Indians within a limited geographical area at Santa Fe, New Mexico.

Accordingly, there will be no impact on any small entities.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of \$100 million or more. The establishment of this Court of Indian Offenses is estimated to cost less than \$200,000 annually to operate. The cost associated with the operation of this court will be shared among the Office of Indian Education, the Bureau of Indian Affairs, and Indian Health Service.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. This is a court established specifically for the administration of misdemeanor justice for Indians located within the boundaries of the Santa Fe Indian School, New Mexico and will not have any cost or price impact on any other entities in the geographical region.

c. 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. This is a court established specifically for the administration of misdemeanor justice for Indians located within the boundaries of the Santa Fe Indian School, New Mexico, and will not have an adverse impact on competition, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.):

a. This rule will not "significantly or uniquely" affect small governments. A Small Government Agency Plan is not required. The establishment of this Court of Indian Offences will not have jurisdiction to affect any rights of the small governments. Its primary function will be to administer justice for misdemeanor offenses within the Santa Fe Indian School grounds. Its jurisdiction will be limited to criminal offense provided in 25 CFR part 11.

b. This rule will not produce a Federal mandate of \$100 million or greater in any year; i.e., it is not a "significant regulatory action" under the Unfunded Mandates Reform Act.

Takings Implication Assessment (Executive Order 12630)

In accordance with Executive Order 12630, the rule does not have significant

takings implications. A takings implication assessment is not required. The amendment to 25 CFR part 11.100(a) will establish a Court of Indian Offences with limited criminal jurisdiction over Indians within a limited geographical area at Santa Fe, New Mexico. Accordingly, there will be no jurisdictional basis for to adversely affect any property interest because the court's jurisdiction is solely personal jurisdiction over Indians.

Federalism (Executive Order 13132)

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. The Solicitor found that authority to rest principally in the statutes placing supervision of the Indians in the Secretary of the Interior, 25 U.S.C. 2 and 9; and 25 U.S.C. 13, which authorizes appropriations for "Indian judges." The United States Supreme Court recognized the authority of the Secretary to promulgate regulations with respect to Courts of Indian Offenses in *United States v. Clapox*, 35 F. 575 (D.Ore. 1888).

Civil Justice Reform (Executive Order 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. The Solicitor analyzed and upheld the Department of the Interior's authority to establish Courts of Indian Offenses in a memorandum dated February 28, 1935. The Solicitor found that authority to rest principally in the statutes placing supervision of the Indians in the Secretary of the Interior, 25 U.S.C. 2 and 9; and 25 U.S.C. 13, which authorizes appropriations for "Indian judges." The United States Supreme Court recognized the authority of the Secretary to promulgate regulations with respect to Courts of Indian Offenses in *United States v. Clapox*, 35 F. 575 (D.Ore. 1888). Part 11 also requires the establishment of an appeals court; hence the judicial system defined in Executive Order 12988 will not normally be involved in this judicial process.

Paperwork Reduction Act

This regulation does not require an information collection under the Paperwork Reduction Act. The information collection is not covered by an existing OMB approval. An OMB form 83-I has not been prepared and has not been approved by the Office of Policy Analysis. No information is being collected as a result of this court

exercising its limited criminal misdemeanor jurisdiction over Indians within the exterior boundaries of the Santa Fe Indian School, New Mexico.

National Environmental Policy Act

We have analyzed this rule in accordance with the criteria of the National Environmental Policy Act and 516 DM. This rule does not constitute a major Federal action significantly affecting the quality of the human environment. An environmental impact statement/assessment is not required. The establishment of this Court of Indian Offenses conveys personal jurisdiction over the criminal misdemeanor actions of Indians with the exterior boundaries of the Santa Fe Indian School and does not have any impact of the environment.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and 512 DM 2, we have evaluated potential effects on federally recognized Indian tribes and have determined that there are no potential effects. The amendment to 25 CFR part 11.100(a) does not apply to any of the 558 federally recognized tribes, except the 19 Pueblos in New Mexico that have requested the establishment of the provisional Court of Indian Offences until they establish a tribal court to provide for a law and order code and judicial system to deal with law and order on the trust land at Santa Fe Indian School. The Department of the Interior, in establishing this provisional court, is fulfilling its trust responsibility and complying with the unique government-to-government relationship that exists between the Federal Government and Indian tribes.

List of Subjects in 25 CFR Part 11

Courts, Indians-Law, Law enforcement, Penalties.

For the reasons stated in the preamble, we are amending part 11, chapter I of title 25 of the Code of Federal Regulations, as set forth below. This amendment is effective from May 3, 2001 to May 1, 2002.

PART 11—LAW AND ORDER ON INDIAN RESERVATIONS

1. The authority citation for part 11 continues to read as follows:

Authority: R.S. 463; 25 U.S.C. 2, 38 Stat. 586; 25 U.S.C. 200, unless otherwise noted.

2. Section 11.100 is amended by adding new paragraph (a)(14) to read as follows:

§ 11.100 Listing of Courts of Indian Offenses.

(a) * * *

(14) Santa Fe Indian School Property, including the Santa Fe Indian Health Hospital (land in trust for the 19 Pueblos of New Mexico).

* * * * *

Dated: April 27, 2001.

James H. McDivitt,

Deputy Assistant Secretary—Indian Affairs (Management).

[FR Doc. 01-11086 Filed 5-2-01; 8:45 am]

BILLING CODE 4310-02-P

Regulatory Information

In order to protect the interests of national security, and in accordance with the Presidential Directive of Jan 31, 2000, the President has directed the conduct of Navy Training at the Atlantic Fleet Weapons Training Facility on Vieques Island, PR. Immediate action is needed to ensure the uninterrupted use by the U.S. Navy of the Training Facility on Vieques, including the adjacent land and waters, and to protect that facility from destruction or injury. The Coast Guard is promulgating the security zone regulations to prevent interference with the conduct of the Navy's exercises for the duration of the security zone. As a result, the enforcement of the security zone is a function directly involved in, and necessary to, the Navy training exercise. Accordingly, based on the military function exception set forth in the Administrative Procedure Act, 5 U.S.C. 553(a)(1), notice and comment rule-making and advance publication, pursuant to 5 U.S.C. 553(b) and (d), are not required for this regulation.

Even if the requirements of 5 U.S.C. 553 would otherwise be applicable, the Coast Guard for good cause finds that, under 5 U.S.C. 553(b)(B) and (d)(3), notice and public comment on the rule before the effective date of the rule and advance publication are impracticable and contrary to the public interest. There is an imminent need to use the naval installation bombing and gunnery range and the adjacent waters for ongoing scheduled exercises by the Navy which further the national security interests of the United States. Opportunity for notice and public comment or advance publication of the zone was impracticable since the Navy did not request the establishment of the zone until April 26, 2001. This regulation is geographically and temporally tailored to meet the needs of national security with a minimal burden on the public.

Background and Purpose

The Atlantic Fleet Weapons Training Facility is located on the eastern end of Vieques Island, PR. Use of this naval installation is important to achieving acceptable levels of military readiness in accordance with established training standards and requires training exercises conducted with inert ordnance. Such training exercises cannot be safely or effectively conducted if there are unauthorized persons inside the training areas or if the installation is damaged or personnel are injured. The U.S. Army Corps of Engineers has established a danger zone in the vicinity of the bombing and

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD07-01-033]

RIN 2115-AA97

Security Zone; Vicinity of Atlantic Fleet Weapons Training Facility, Vieques, PR and Adjacent Territorial Sea

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: At the request of the U.S. Navy, the Coast Guard is establishing a temporary security zone covering the area of territorial sea and land adjacent to the bombing and gunnery range (Impact Area) at the naval installation on the eastern end of Vieques Island, Puerto Rico. The security zone is needed to protect the bombing and gunnery range, and adjacent land and waters at the Navy's Atlantic Fleet Weapons Training Facility on Vieques Island, PR, to ensure against destruction, injury, or loss of uninterrupted use. Only authorized vessels are permitted to enter or remain within the security zone.

DATES: This rule is effective from 3 p.m., April 26, 2001 until 11:59 p.m., April 30, 2001.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket [CGD07-01-033] and are available for inspection or copying at the Seventh Coast Guard District office, 909 S.E. First Avenue, Room 918, Miami, FL, 33131, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

LTJG Brian DeVries at (305) 415-6950.

SUPPLEMENTARY INFORMATION: