

(1) Starting at a speed sufficiently above the minimum steady flight speed to ensure that a steady rate of speed reduction can be established, apply the longitudinal control so that the speed reduction does not exceed one knot per second until the control reaches the stop.

(2) The longitudinal control must be maintained at the stop until the airplane has reached a stabilized flight condition and then recovered by normal recovery techniques.

(3) The requirements for turning flight maneuver demonstrations must also be met with accelerated rates of entry to the incidence limit, up to the maximum rate achievable.

6. Characteristics in High Incidence Maneuvers—In lieu of the requirements of § 25.203, the following special condition is issued:

(a) Throughout maneuvers with a rate of deceleration of not more than 1 knot per second, both in straight flight and in 30 degree banked turns, the airplane's characteristics must be as follows:

(1) No abnormal airplane nose-up pitching.

(2) No uncommanded nose-down pitching (which is indicative of stall). However, reasonable attitude changes associated with stabilizing the incidence at alpha limit as the longitudinal control reaches the stop is acceptable. Any reduction of pitch attitude associated with stabilizing the incidence at the alpha limit should be achieved smoothly and at a low pitch rate, so it is not likely to be mistaken for natural stall identification.

(3) No uncommanded lateral or directional motion, and the pilot must retain good lateral and directional control by conventional use of the cockpit controls throughout the maneuver.

(4) The airplane must not exhibit buffeting of a magnitude or severity that would act as a deterrent to completing the maneuver specified in § 25.201(a) as amended by this special condition.

(b) In maneuvers with increased rates of deceleration, some degradation of characteristics associated with a transient excursion beyond the stabilized alpha-limit is acceptable. However, the airplane must not exhibit dangerous characteristics or characteristics that would deter the pilot from holding the longitudinal control on the aft stop for a period of time appropriate to the maneuvers.

(c) It must always be possible to reduce incidence by conventional use of the longitudinal control.

(d) The rate at which the airplane can be maneuvered from trim speeds associated with scheduled operating

speeds, such as V_2 and V_{REF} up to alpha-limit, should not be unduly damped or significantly slower than can be achieved on conventionally controlled transport airplanes.

7. Atmospheric Disturbances—Operation of the high incidence protection function must not adversely affect aircraft control during expected levels of atmospheric disturbances, nor impede the application of recovery procedures in case of windshear. Simulator tests and analysis may be used to evaluate such conditions, but must be validated by limited flight testing to confirm handling qualities at critical loading conditions.

8. Longitudinal Control—In lieu of the requirements of § 25.145(a), (a)(1) and (b)(6), the following special conditions are issued:

(a) It must be possible, at any point between the trim speed prescribed in § 25.103(b)(6) as amended by this special condition and V_{min} , to pitch the nose downward so that the acceleration to this selected trim speed is prompt.

(b) With the landing gear extended, no change in trim control, or exertion of more than 50 pounds control force (representative of the maximum short-term force that can be applied readily by one hand) may be required for the following maneuver: With power off, flaps extended and the airplane trimmed at $1.3 V_{SR1}$, obtain and maintain airspeeds between V_{min} and either $1.6 V_{SR1}$ or V_{FE} , whichever is lower.

9. Airspeed Indicating System—In lieu of § 25.1323(c)(1) and (c)(2), the following special conditions are issued:

(a) V_{MO} to V_{min} with the flaps retracted; and

(b) V_{min} to V_{FE} with flaps in the landing position.

Issued in Renton, Washington, on March 18, 2011.

KC Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 529

[Docket No. FDA-2011-N-0003]

New Animal Drugs; Oxytetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The supplemental ANADA provides for use of oxytetracycline hydrochloride soluble powder for control of American and European fowlbrood in honey bees and for skeletal marking of finfish fry and fingerlings.

DATES: This rule is effective March 28, 2011.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed a supplement to ANADA 200-026 that provides for use of PENNOX 343 (oxytetracycline HCl) Soluble Powder for control of American and European fowlbrood in honey bees and for skeletal marking of finfish fry and fingerlings by immersion. The supplemental ANADA is approved as of December 6, 2010, and the regulations in 21 CFR 520.1660d and 529.1660 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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 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 the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Parts 520 and 529

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 parts 520 and 529 are 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.

§ 520.1660d [Amended]

■ 2. In paragraph (b)(6) of § 520.1660d, remove “cattle, and sheep” and in its place add “cattle, sheep, and honey bees.”

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.1660 [Amended]

■ 4. In paragraph (b)(2) of § 529.1660, remove “Nos. 000069 and 059130” and in its place add “Nos. 000069, 048164, and 059130”.

Dated: March 23, 2011.

David Dorsey,

*Acting Deputy Commissioner for Policy,
Planning and Budget.*

[FR Doc. 2011-7216 Filed 3-25-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 558

[Docket No. FDA-2011-N-0003]

New Animal Drugs; Arsanilate Sodium; Sulfaethoxyypyridazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove sections pertaining to use of arsanilate sodium and sulfaethoxyypyridazine in medicated feed because there are no currently approved new animal drug applications (NADAs) for such uses. Conforming amendments are also being made. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective March 28, 2011.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug

Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, e-mail: *George.Haibel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA has determined the animal drug regulations describe conditions of use for arsanilate sodium and sulfaethoxyypyridazine in medicated feed for which no NADA is currently approved.

1. *Arsanilate sodium* § 558.60 (21 CFR 558.60). In the **Federal Register** of December 18, 1986 (51 FR 45346), FDA proposed to remove § 558.20 *Drugs used in medicated feeds in use before January 1, 1958, which are not otherwise listed; interim listing* (21 CFR 558.20) because this section in part 558 subpart A—*General Provisions* did not provide an appropriate basis upon which to approve medicated feed applications and because several of the drugs listed were not the subject of approved NADAs. Among other exceptions, FDA proposed to transfer the arsanilate sodium provisions of § 558.20 to § 558.60 in subpart B—*Specific New Animal Drugs for Use in Animal Feeds* (subpart B) to reflect their status as approved conditions of use.

In 1991, FDA issued a final rule removing most of § 558.20 (56 FR 19263, April 26, 1991) and codifying approved uses in subpart B. Elsewhere in the same issue of the **Federal Register**, FDA repropoed the removal of the remaining portions of § 558.20 that pertained to certain uses of arsanilate sodium (56 FR 19332, April 26, 1991). FDA repropoed those portions of the rule because it recognized that some of the uses it had proposed to codify in subpart B did not appear to be the subject of approved NADAs, as previously stated. In the discussion of the repropoed changes, FDA tentatively concluded that NADA 8-966 for arsanilate sodium for use in swine feed was voluntarily withdrawn by a letter dated November 12, 1973. The Agency acknowledged this withdrawal by a letter dated January 16, 1974 (*see* 56 FR 19332 at 19333, Refs. 1 and 2).

In 1992, FDA issued a final rule removing the remaining portions of § 558.20 (57 FR 1641, January 15, 1992) and noted that no evidence or comments were received on the 1991 repropoed rule, which had requested that anyone claiming to hold an approved NADA for arsanilate sodium in swine feed submit evidence to substantiate the approval. FDA concluded that NADA 8-966 providing for use of arsanilate sodium in medicated feeds for swine was voluntarily withdrawn at the request of the sponsor (*see* 56 FR 19332 and Refs. 1 and 2 of the repropoed).

After careful review of its NADA records, FDA has concluded that all uses of arsanilate sodium in medicated feeds in NADA 8-966 were voluntarily withdrawn by the sponsor in 1973 and that there is no currently approved NADA providing for the use of arsanilate sodium in medicated feed or in any dosage form. Accordingly, the animal drug regulations in part 558 (21 CFR part 558) are amended by removing § 558.60. Conforming amendments are also being made in §§ 558.55 and 558.680 by removing reference to use in combination with amprolium and zoalene, respectively. This action is being taken to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and to improve the accuracy of the regulations.

2. *Sulfaethoxyypyridazine* (§§ 558.579). In 1966, FDA approved a food additive petition and codified the safe use of sulfaethoxyypyridazine in feed and drinking water of swine at § 121.280 (21 CFR 121.280) (31 FR 2425 at 2426, February 5, 1966). In 1968, § 121.280 was amended to add use in cattle in feed and water, and by tablet and injection, and to make all uses, including use in feed restriction to “for sale by or on the order of a licensed veterinarian” (33 FR 627 at 628, January 18, 1968). A 1969 amendment revised that use restriction to read “for use by or on the order of a licensed veterinarian” (34 FR 20272, December 25, 1969).

In a 1976 reorganization of certain food additive regulations from 21 CFR part 121 to new part 558 *New Animal Drugs For Use in Animal Feed*, § 121.280 was redesignated as § 558.579 (41 FR 10983 at 11005, March 15, 1976). In the intervening 35 years there have been no required annual drug experience reports, or any product stability reports, submitted for any NADA for use of sulfaethoxyypyridazine in medicated feed. At this time and after careful review of its NADA records, FDA has concluded that there is no approved NADA for the use of sulfaethoxyypyridazine in medicated feed for swine or cattle. Accordingly, the animal drug regulations in part 558 are amended by removing § 558.579. A conforming amendment is also being made in 21 CFR 522.2240 to remove a provision for administration of sulfaethoxyypyridazine injectable solution followed by use of sulfaethoxyypyridazine medicated cattle feed. This action is being taken to comply with the FD&C Act and to improve the accuracy of the regulations.

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.”