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:

§ 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:

§ 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”.


David Dorsey
Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–7236 Filed 3–25–11; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 558


New Animal Drugs; Arsanilate Sodium; Sulfaethoxypyridazine

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 sulfaethoxypyridazine 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 sulfaethoxypyridazine 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 reproposed the removal of the remaining portions of § 558.20 that pertained to certain uses of arsanilate sodium (56 FR 19322, April 26, 1991). FDA reproposed 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 reproposed 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 19322 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 reproposed 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 19322 and Refs. 1 and 2 of the reproposal).

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. Sulfaethoxypyridazine (§§ 558.579).

In 1966, FDA approved a food additive petition and codified the safe use of sulfaethoxypyridazine 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 sulfaethoxypyridazine 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 sulfaethoxypyridazine 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 sulfaethoxypyridazine injectable solution followed by use of sulfaethoxypyridazine 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.”
Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects
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 the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 522 and 558 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

§ 522.2240 Sulfaethoxypyridazine.

* * *

(e) * * *

(3) Limitations. Administer intravenously for not more than 4 days; or first treatment may be followed by 3 days of treatment with sulfaethoxypyridazine in drinking water or tablets in accordance with § 520.2240a(e) and 520.2240b(e) of this chapter; as sodium sulfaethoxypyridazine; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§ 558.60 [Removed]
6. Remove § 558.60.

§ 558.579 [Removed]
7. Remove § 558.579.

§ 558.680 [Amended]
8. In § 558.680, in the tables in paragraphs (d)(1)(i), (d)(1)(ii), and (d)(1)(iii), remove the entries for “Arsanilate sodium 90 (0.01%)”.


David Dorsey, Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–7214 Filed 3–25–11; 8:45 am]
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DEPARTMENT OF STATE
22 CFR Part 62
[Public Notice: 7346]
RIN 1400–AC67

Exchange Visitor Program—Fees and Charges

Correction
In rule document 2011–4276, appearing on pages 10498–10500 in the issue of Friday, February 25, 2011, make the following correction:

On page 10498, in the second column, in the DATES section, “Effective Date: This rule is effective 30 days from February 25, 2011” should read “Effective Date: This rule is effective March 28, 2011”.

[FR Doc. C1–2011–4276 Filed 3–25–11; 8:45 am]
BILLING CODE 1505–01–D

DEPARTMENT OF THE INTERIOR
National Park Service
36 CFR Part 7
RIN 1024–AD96

Special Regulation: Areas of the National Park System, National Capital Region

AGENCY: National Park Service, Interior.
ACTION: Final rule.

SUMMARY: The National Park Service (NPS) is physically moving the office of the Division of Park Programs, National Mall and Memorial Parks (NAMA) which processes applications for special events and demonstrations permits for nine parks in the National Capital Region (NCR). This rule updates the address and location of the office where these permit applications may be obtained and where completed applications are to be submitted by mail or in person.

DATES: Effective March 28, 2011.

FOR FURTHER INFORMATION CONTACT: Robbin M. Owen, Chief, Division of Park Programs, National Park Service, National Capital Region, 900 Ohio Drive SW., Washington, DC 20024. Telephone: (202) 619–7225.

SUPPLEMENTARY INFORMATION: During the fourth week of March, the NPS is expecting to move the Division of Park Programs from 1100 Ohio Drive, SW., to the nearby 900 Ohio Drive, SW., Washington, DC 20024. Now codified at 36 CFR 7.96(g)(3), the NPS 1975 rulemaking established a centralized location where permit applications for special events and demonstrations, must be submitted, Monday—Friday from 8 a.m. to 4 p.m., holidays excepted. As the NPS explained the NCR regulatory permit application process the: Applications will be immediately date-and-time stamped upon receipt. * * * This provision for official receipt only during office hours is designed to permit the Park Service to properly process applications within the prescribed time period. 40 FR 58652 (1975)

As Acting Secretary of the Interior Nathaniel P. Reed explained, at 41 FR 12880 (1976):

It is the opinion of the Department that receipt of the application in this single location is necessary in order to effectively administer the priority system for the use of park lands, to ensure that the application will be considered by an official of responsible rank, and to allow for consideration of the permit within the applicable time limitation. Even though executed permit applications must be received at that location, application blanks may be obtained at other locations in the National Capital Parks area. * * *

As to why applications had to be received at the permit offices during regular business hours, the NPS explained at 41 FR 12880 (1976), that: [T]his limitation is necessary in order that the required security precautions and augmentation of forces and services may be provided. The Department has weighed the administrative burdens that the absence of this limitation would impose upon the various government agencies involved against possible effects upon the exercise of First Amendment freedoms and believes on balance that these effects are inconsequential. This impact is further lessened since demonstrations may be conducted in certain areas without permit pursuant to paragraph (b).

Need for Change: The technical amendment is needed to provide the public with the new address of the relocated permit office where special