the labeling. Transfer an accurately measured representative portion of the suspension equivalent to one dose into a 200-milliliter volumetric flask. Add 10 milliliters of methanol and disperse the sample. Dilute to volume with methanol. Dilute 20.0 milliliters of this solution to volume in a 50-milliliter volumetric flask with deionized water, swirl to mix, and allow to stand for 10 minutes. (Note: A white turbidity is formed.) Filter this solution via a suitable disposable filter unit, discarding the first 5 milliliters. Store for no more than 8 hours under refrigeration and protect from light.

(iii) *Calculations*. Calculate the milligrams of cefuroxime per dose (5 milliliters) as follows:

$$\text{Milligrams of cefuroxime per 5 milliliters of sample} = \frac{A_U \times P_S \times d}{A_S \times 1{,}000}$$

where:

A_U = Sum of the areas of the cefuroxime axetil sample isomer A and isomer B peaks;

A_S = Sum of the peak areas of the cefuroxime axetil working standard isomer A and isomer B peaks;

P_S = Cefuroxime activity in the cefuroxime axetil working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(2) *Dissolution*. Proceed as directed in § 436.215 of this chapter. The quantity Q (the amount of cefuroxime activity dissolved) is 60 percent at 30 minutes.

(3) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(4) *pH*. Reconstitute as directed in the labeling and proceed as directed in § 436.202 of this chapter.

(5) *Identity*. The high-performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the cefuroxime axetil working standard.

Dated: May 9, 1995.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95–12604 Filed 5–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

[Docket No. 95N–0096]

Implantation or Injectable Dosage Form New Animal Drugs; Guaifenesin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of the animal drug name from glyceryl guaiacolate to guaifenesin. This amendment is an administrative change to redesignate glyceryl guaiacolate products as guaifenesin products.

EFFECTIVE DATE: May 23, 1995.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 30, 1972 (37 FR 12936) and November 5, 1976 (41 FR 48732), FDA published final rules which reflected approval of injectable glyceryl guaiacolate products. In the **Federal Register** of December 10, 1984 (49 FR 48038), FDA published a final rule which reflected approval of a guaifenesin powder for injection. Guaifenesin is the newer chemical name for glyceryl guaiacolate. At the time of the December 10, 1984, approval, the prior approvals were not amended to reflect the newer chemical name. FDA is amending the regulations in part 522 (21 CFR part 522) to reflect the newer chemical name by removing §§ 522.1060, 522.1060a, and 522.1060b; by adding a new sponsor to § 522.1085; and by adding new § 522.1086 *Guaifenesin injection*.

FDA has determined under 21 CFR 25.24(a)(9) 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.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1060 [Removed]

2. Section 522.1060 *Glyceryl guaiacolate implantation or injectable dosage forms* is removed.

§ 522.1060a [Removed]

3. Section 522.1060a *Glyceryl guaiacolate sterile powder* is removed.

§ 522.1060b [Removed]

4. Section 522.1060b *Glyceryl guaiacolate injection* is removed.

§ 522.1085 [Amended]

5. Section 522.1085 *Guaifenesin sterile powder* is amended in paragraph (b) by removing ''000031'' and adding in its place the phrase ''000031 and 037990''.

6. New § 522.1086 is added to read as follows:

§ 522.1086 Guaifenesin injection.

(a) *Specifications*. Each milliliter of sterile aqueous solution contains 50 milligrams of guaifenesin and 50 milligrams of dextrose.

(b) *Sponsor*. See No. 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used intravenously in horses as a skeletal muscle relaxant.

(2) Administer rapidly at a dosage of 1 milliliter per pound of body weight.

(3) No to be used in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 5, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–12506 Filed 5–22–95; 8:45 am]

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DEPARTMENT OF EDUCATION

34 CFR Parts 78, 208, 215, 230, 232, 233, 234, 236, 238, 241, 245, 246, 247, 250, 251, 252, 253, 254, 255, 256, 257, 258, 282, 298, 346, 347, 354, 362, 372, 374, 405, 407, 408, 409, 414, 416, 417, 418, 419, 422, 423, 424, 445, 462, 463, 471, 473, 474, 475, 476, 500, 501, 520, 524, 525, 526, 537, 538, 548, 555, 561, 573, 574, 581, 629, 665, 671, 673, 691, 698, 700, 706, 707, 708, 722, 750, 755, 757, 758, 760, 761, 762, 763, 768, 773, 778, 779, and 790

Removal of Regulations

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the Code of Federal Regulations (CFR) to remove unnecessary and obsolete regulations. As a result of new legislation, absence of funding, and review in accordance with the President's regulatory reinvention initiative, the Secretary has determined