

production day for such 12-month period, there is a rebuttable presumption that the well produced at its maximum efficient rate of flow.

(ii) If such 12-months' production data established that the well produced natural gas at a rate which did not exceed an average of 70 Mcf per production day for such 12-month period, the jurisdictional agency shall make a deferred determination in accordance with paragraph (c).

(2) *Prior production data not available.* If production data are not available for the 12-month period ending concurrently with such 90-day production period, the jurisdictional agency shall make a deferred determination in accordance with paragraph (c).

(3) *Other evidence.* The jurisdictional agency may base the determination upon other substantial evidence, such as flow tests, which measure the capability of the well to produce natural gas under normal operating conditions.

(c) *Deferred determination procedure.* If a determination is deferred under paragraph (b)(1)(ii) or (b)(2), the jurisdictional agency shall designate a 12-month period during which the applicant may secure the data establishing that the well produced natural gas at an average rate not in excess of 60 Mcf per production day. The applicant may submit such data not later than 90 days after the close of such 12-month period, and if such data show that the well's production did not exceed 60 Mcf per production day, the jurisdictional agency shall make an affirmative determination.

(d) *Negative determinations.* The jurisdictional agency shall make a negative determination as to eligibility if:

(1) The production data submitted by the applicant indicate that for the 12 months ending concurrently with the 90-day production period the well produced natural gas at a rate which exceeded an average of 70 Mcf per production day, unless the jurisdictional agency determines that the well produced at its maximum efficient rate of flow pursuant to paragraph (a)(1) or paragraph (b)(3).

(2) The production data submitted by the applicant indicate that for the deferred 12-month period established by the jurisdictional agency, the well produced natural gas at a rate which exceeded an average of 60 Mcf per production day, or

(3) The applicant fails to submit available production data pursuant to paragraph (b)(1) or fails to submit production data pursuant to paragraph (c).

(e) *Interim collection.* When the jurisdictional agency defers making a determination on an application pursuant to paragraph (b)(1)(ii) or (b)(2), the applicant shall be permitted to make interim collections of the maximum lawful price provided in § 271.802 pursuant to the requirements of § 273.202. If the filing requirements of § 273.202(d) have previously been complied with, the applicant shall not be required to make such filings again.

PART 274—DETERMINATIONS BY JURISDICTIONAL AGENCIES

2. Part 274 is amended in § 274.206(a) (3), (4), (5) and (6) to read as follows:

§ 274.206 Stripper well natural gas.

A person seeking a determination for purposes of Subpart H of Part 271 that a well either qualifies or continues to qualify as a stripper well shall file an application with the jurisdictional agency which contains the following items:

(3) Where the maximum efficient rate of flow for the well has not been previously established;

(i) Production records, if available, and if not tax records, if available, or verified copies of billing statements for the 12 months ending on the last day of the 90-day production period upon which the application is based; or

(ii) A copy of the results of any tests which measure the production capability of the well, or any other evidence as the applicant may submit upon which the jurisdictional agency could establish maximum efficient rate of flow.

(4) Where the determination is deferred pursuant to § 271.807 (b)(1)(ii) or (b)(2), within 90 days after the last day of the deferred period, production data for the deferred period, including the 90-day production period upon which the application is based.

(5) The number of days natural gas was produced during the 90-day production period described in § 271.803(c)(2).

(6) The number of days natural gas was not produced during the 90-day production period described in § 271.803(c)(2), and

(i) A description of the state law or conservation practice, as set forth in § 271.803(d)(2), pursuant to which the well did not produce on any such day or days, or

(ii) An explanation of any other reason the well did not produce on any such day or days.

3. Section 274.206(a) is amended by redesignating subparagraph (6) as

subparagraph (7), subparagraph (7) as subparagraph (8), subparagraph (8) as subparagraph (9), and subparagraph (9) as subparagraph (10).

4. Section 274.206(a) is amended in redesignated subparagraph (9) by deleting the phrase "person signing the application," and inserting in lieu thereof the word "applicant,".

5. Section 274.206(b) is amended in subparagraph (5) by deleting "§ 271.805" and inserting in lieu thereof "§ 271.805(a)(3)".

6. Sections 274.206(c) and 274.206(d) are amended in subparagraphs (4) and (5) respectively by deleting the phrase "the appropriate entities specified in § 271.805" and inserting in lieu thereof the phrase "the jurisdictional agency, the Commission, and any purchaser".

[FR Doc. 79-26460 Filed 8-23-79; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

Adverse Effect Wage Rate for Agricultural Employment in the State of Colorado; Correction

AGENCY: Employment and Training Administration, Labor.

ACTION: Final rule; correction.

SUMMARY: On August 10, 1979, a final rule was published in the *Federal Register*, at 44 FR 47040, amending 20 CFR § 655.207(b)(2), by adding the State of Colorado to the list of States for which adverse effect wage rates are computed and published annually. The State of Vermont was inadvertently left off the list. As corrected, 20 CFR § 655.207(b)(2) reads as follows:

§ 655.207 Adverse effect rates.

(b) ***

(2) *List of States.* Colorado, Connecticut, Maine, Maryland, Massachusetts, New Hampshire, New York, Rhode Island, Texas, Vermont, Virginia, and West Virginia. Other States may be added as appropriate.

FOR FURTHER INFORMATION CONTACT:

Aaron Bodin, Chief, Division of Labor Certification, Office of Technical Services, ETA, Department of Labor, Telephone: 202-376-6295.

(Secretary of Labor's Order No. 4-75, 40 FR 18515)

Signed at Washington, D.C. this 16th day of August, 1979.

Ernest G. Green,

Assistant Secretary for Employment and Training.

[FR Doc. 79-26484 Filed 8-23-79; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 105

[Docket No. 75N-0107]

Foods for Special Dietary Use; Vitamin and Mineral Products; Revocation of Regulations

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

SUMMARY: The Food and Drug Administration amends the food regulations by deleting a certain provision concerning the use and labeling of saccharin. The agency is taking this action to correct a previously published order reinstating regulations that were no longer superseded because the U.S. Court of Appeals for the Second Circuit ruled the superseding regulations invalid. The reinstated regulations include a provision that conflicts with another regulation promulgated in the interim.

EFFECTIVE DATE: August 24, 1979.

FOR FURTHER INFORMATION CONTACT: L. Robert Lake, Bureau of Foods (HFF-302), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1254.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 16, 1979 (44 FR 16005), FDA revoked certain definitions, standards, and labeling regulations relating to dietary supplements of vitamins and minerals because of a court ruling pointing out procedural deficiencies in their issuance. Although FDA intends to repropose those regulations, there was a need to fill (on an interim basis) some of the gaps created by the court mandated revocation. Therefore, the March 16 document reinstated certain provisions that were to have been superseded by the regulations being revoked.

The March 16 document inadvertently reinstated one paragraph, § 105.3(d) (21 CFR 105.3(d)), that contains saccharin labeling provisions inconsistent with another regulation. Paragraph (b) of § 105.66 *Label statements relating to usefulness in reducing or maintaining caloric intake or body weight* (21 CFR

105.66), published in the Federal Register of September 22, 1978 (43 FR 43248), now addresses the labeling of such nonnutritive ingredients.

§ 105.3 [Amended]

Therefore, under the decision by the court, the Commissioner of Food and Drugs hereby orders that § 105.3 *Definitions and Interpretations* be amended by deleting and reserving paragraph (d).

Because the order corrected by this final rule is a ministerial act revoking regulations already ruled invalid by a court and because it relieves a restriction and there is no useful purpose in postponing the effective date, the Commissioner concludes, under the Administrative Procedure Act (5 U.S.C. 553(b)(B) and (d) (1) and (3)), that notice and public procedure and delayed effective date are unnecessary.

Executive Order 12044 on improving government regulations requires the agency to consider economic impacts in the development of regulations. Because this action is being taken to revoke regulations that a court has already invalidated, no assessment of its economic impact has been made. No economic impacts are expected to occur from the revocation because no new requirements are imposed at this time. The economic impact of vitamin and mineral supplement standards and labeling regulations will be evaluated in the course of reissuing these regulations through the normal rulemaking procedure.

EFFECTIVE DATE. This regulation is effective August 24, 1979.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26353 Filed 8-23-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Parts 520 and 522

[Docket No. 79N-0271]

Chlorpromazine Hydrochloride, Chlorpromazine Hydrochloride Injection

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

SUMMARY: This document amends the regulations for chlorpromazine hydrochloride and chlorpromazine hydrochloride injection to indicate those conditions of use for which approvals for identical products need not include certain types of efficacy data. These conditions of use were classified as

probably effective as a result of a National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group evaluation of the products. In lieu of certain efficacy data, approval may require submission of bioequivalence or similar data. An earlier Federal Register publication has reflected that these products are in compliance with the conclusions of the review.

EFFECTIVE DATE: August 24, 1979.

FOR FURTHER INFORMATION CONTACT:

Donald A. Gable, Bureau of Veterinary Medicine (HFV-100), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4313.

SUPPLEMENTARY INFORMATION: The NAS/NRC review of these products was published in the Federal Register of November 18, 1969 (34 FR 18394). In that document, the Academy concluded, and the Food and Drug Administration agreed, that the products were probably effective as tranquilizers for veterinary use.

That announcement was issued to inform holders of new animal drug applications (NADA's) of the findings of the Academy and the agency, and to inform all interested persons that such articles could be marketed if they were the subject of approved NADA's and otherwise complied with the requirements of the Federal Food, Drug, and Cosmetic Act.

Pitman-Moore, Inc., Washington Crossing, NJ 08560, responded to the notice by submitting a supplemental NADA (10-905V) providing current information covering manufacturing and controls and revising the labeling for the safe and effective use of the products as tranquilizers for animals. The supplemental application was approved by a regulation published in the Federal Register of March 5, 1973 (38 FR 5841). The regulation reflecting this approval established a new section for the drug in tablet form (21 CFR 135c.105, recodified at 21 CFR 520.443) and a new section for the drug in the injectable form (21 CFR 135b.80, recodified at 21 CFR 522.443). The new sections did not specify those conditions of use that were NAS/NRC approved.

This document amends the regulations to indicate those conditions of use for which approval for identical products need not include certain types of efficacy data required for approval by § 514.111(a)(5)(vi) of the new animal drug regulations. In lieu of those data, approval of such products may be obtained if bioequivalency or similar data are submitted as suggested in the

guideline for submitting NADA's for generic drugs reviewed by the NAS/NRC. The guideline is available from the office of the Hearing Clerk (HFA-305), Rm. 4-65, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Parts 520 and 522 are amended as follows:

1. In Part 520, § 520.443 is amended by adding after paragraph (c) (1), (2), (3), and (4) the footnote reference "1" and by adding at the end of the section the footnote to read as follows:

§ 520.443 Chlorpromazine hydrochloride.

- (c) *Conditions of use.* (1) * * * 1
(2) * * * 1
(3) * * * 1
(4) * * * 1

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

2. In Part 522, § 522.443 is amended by adding after paragraph (c) (1), (2), (3), and (4) the footnote reference "1" and by adding at the end of the section the footnote to read as follows:

§ 522.443 Chlorpromazine hydrochloride injection.

- (c) *Conditions of use.* (1) * * * 1
(2) * * * 1
(3) * * * 1
(4) * * * 1

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter but may require bioequivalency and safety information.

Effective date. This regulation is effective August 24, 1979.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(1)).)

Dated: August 16, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79-26029 Filed 8-23-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 524

[Docket No. 79N-0300]

Ophthalmic and Topical Dosage Form New Animal Drugs Not Subject to Certification; Neomycin Sulfate Ophthalmic Ointment

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect approval of a supplemental new animal drug application (NADA) providing that safe and effective use of neomycin sulfate ophthalmic ointment in dogs and cats be restricted to use by or on the order of a veterinarian. The application was filed by Evsco Pharmaceutical Corp.

EFFECTIVE DATE: August 24, 1979.

FOR FURTHER INFORMATION CONTACT: Bob G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Evsco Pharmaceutical Corp., P.O. Box 209, Buena, NJ 08310, filed a supplemental NADA (44-655) providing for a change from over-the-counter (OTC) to prescription drug status for its Neomycane product (neomycin-sulfate ophthalmic ointment). Proper treatment of eye infections involve clinical diagnosis and laboratory tests before treatment. The ability of a lay person to recognize infections of the conjunctiva and eliminate ocular syndromes and infections which would be unresponsive to neomycin therapy is questionable. Therefore, the conditions of use of this drug are restricted to use by or on the order of a licensed veterinarian. The approval of this supplement improves the animal safety and effectiveness of the product by moving the drug from OTC to prescription status. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy, the approval did not require a reevaluation of the underlying safety and effectiveness data in the parent application.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), § 524.1484a is amended by adding new paragraph (c)(6) to read as follows:

§ 524.1484a Neomycin sulfate ophthalmic ointment.

* * * * *

(c) * * *

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

EFFECTIVE DATE: This amendment is effective August 24, 1979.

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

Dated: August 16, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79-26355 Filed 8-23-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 540

Penicillin Antibiotic Drugs for Animal Use; Procaine Penicillin G Aqueous Suspension (Injectable)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) providing for safe and effective use of injectable procaine penicillin G aqueous suspension for treating cattle, sheep, swine, and horses. The application, filed by Maurry Biological Co., is in compliance with the conclusions of the National Academy of Sciences—National Research Council (NAS/NRC) evaluation of the product.

EFFECTIVE DATE: August 24, 1979.

FOR FURTHER INFORMATION CONTACT: John R. Quast, Bureau of Veterinary Medicine (HFV-123), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442.

SUPPLEMENTARY INFORMATION: Maurry Biological Co., Inc., 6109 South Western Ave., Los Angeles, CA 90047, is the holder of NADA 65-010 for an injectable procaine penicillin G aqueous suspension used for treating infections in cattle, sheep, swine, and horses. This application was originally approved November 27, 1956. It was one of several that were the subject of a NAS/NRC evaluation published in the *Federal Register* of August 25, 1970 (35 FR 13544). In that document NAS/NRC concluded, and the agency concurred, that the injectable procaine penicillin G aqueous suspension products are probably effective in animals for intramuscular use in treating infections caused by pathogens sensitive to procaine penicillin G. The document, however, identified certain deficiencies