

(4) After Federal salary offset begins, the debtor may request a reduction in the amount deducted from disposable pay each payday. When we determine that the amount deducted causes financial harm under the rules in § 422.415(b), (c), and (d) of this chapter, we will reduce that amount.

(e) *Refunds.* We will promptly refund to the debtor any amounts collected that the debtor does not owe. Refunds do not bear interest unless required or permitted by law or contract.

■ 5. Section 422.317 is revised to read as follows:

§ 422.317 Review of the debt.

(a) *Notification and presentation of evidence by the debtor.* A debtor who receives a notice described in § 422.305(b), § 422.306(b), or § 422.310(c) has a right to have a review of the debt and the payment schedule for Federal salary offset stated in the notice. To exercise this right, the debtor must notify us and give us evidence that he or she does not owe all or part of the debt, or that we do not have the right to collect it, or that the payment schedule for Federal salary offset stated in the notice would cause financial hardship.

(1) If the debtor notifies us and presents evidence within 60 calendar days from the date of our notice (except as provided for Federal salary offset in paragraph (a)(3) of this section), we will not take the action described in our notice unless and until review of all of the evidence is complete and we send the debtor the findings that all or part of the debt is overdue and legally enforceable.

(2) If the debtor notifies us and presents evidence after that 60 calendar-day period expires (except as provided for Federal salary offset in paragraph (a)(4) of this section) and paragraph (b) of this section does not apply, the review will occur, but we may take the actions described in our notice without further delay.

(3) If the debtor notifies us and presents evidence within 30 calendar days from the date of our notice, we will not refer the debt for Federal salary offset unless and until review of all of the evidence is complete and we send the debtor the findings that all or part of the debt is overdue and legally enforceable and (if appropriate) the findings on the payment schedule for Federal salary offset.

(4) If the debtor notifies us and presents evidence after that 30 calendar-day period expires and paragraph (b) of this section does not apply, the review will occur, but we may refer the debt for

Federal salary offset without further delay.

(b) *Good cause for failure to timely request review.*

(1) If we decide that the debtor has good cause for failing to request review within the applicable period mentioned in paragraphs (a)(1) and (a)(3) of this section, we will treat the request for review as if we received it within the applicable period.

(2) We will determine good cause under the rules in § 422.410(b)(1) and (2) of this chapter.

(c) *Review of the evidence.* The review will cover our records and any evidence and statements presented by the debtor.

(d) *Special rules regarding Federal salary offset.*

(1) When we use Federal salary offset to collect a debt owed by an employee of the Federal Government, an official designated in accordance with 5 U.S.C. 5514(a)(2) will conduct the review described in this section and will issue the findings.

(2) In addition to the requirements in paragraphs (a) and (b) of this section, the Federal employee must submit the request for review in writing. The request must

- (i) Be signed by the employee,
- (ii) Explain with reasonable specificity the facts and evidence that support the employee's position, and
- (iii) Include the names of any witnesses.

(3) In reviewing the payment schedule described in the notice to the Federal employee, the reviewing official must apply the rules in § 422.415(b), (c), and (d) of this chapter regarding financial hardship.

(4) The reviewing official will review our records and any documents, written statements, or other evidence submitted by the debtor and issue written findings.

(5) The reviewing official will complete the review within 60 calendar days from the date on which the request for review and the debtor's evidence are received. If the reviewing official does not complete the review within that 60-day period and the debt was referred to the Department of the Treasury for Federal salary offset, we will notify the Department of the Treasury to suspend Federal salary offset. Offset will not begin or resume before we send the debtor findings that all or part of the debt is overdue and legally enforceable or (if appropriate) findings on the payment schedule.

(e) *The findings.*

(1) Following the review described in paragraphs (c) or (d) of this section, we will send the written findings to the debtor. The findings will state the nature and origin of the debt, the

analysis, findings and conclusions regarding the amount and validity of the debt, and, when appropriate, the repayment schedule for Federal salary offset. Issuance of these findings will be the final action on the debtor's request for review.

(2) If the findings state that an individual does not owe the debt, or the debt is not overdue, or we do not have the right to collect it, we will not send information about the debt to consumer or other credit reporting agencies or refer the debt to the Department of the Treasury for administrative offset. If we had referred the debt to the Department of the Treasury for administrative offset, we will cancel that action. If we had informed consumer or credit reporting agencies about the debt, we will inform them of the findings.

(3) If the findings state that the payment schedule for Federal salary offset would cause financial hardship, we will notify the debtor and the Department of the Treasury of the new payment schedule.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Liquid

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 Med-Pharmex, Inc. The supplemental ANADA provides for revisions to labeling for ivermectin liquid, administered by mouth or nasogastric tube to horses for treatment and control of various internal parasites or parasitic conditions.

DATES: This rule is effective July 5, 2006.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9808, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861, filed a

supplement to ANADA 200–292 for IVERSOL (ivermectin) Liquid for Horses for the oral treatment and control of various species of internal parasites or parasitic conditions. The supplement provides for revisions to label indications and to the food safety warning. The supplemental ANADA is approved as of May 30, 2006, and 21 CFR 520.1195 is amended to reflect the approval.

Approval of this supplemental ANADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(1) 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 Part 520

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 520 is 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.

§ 520.1195 [Amended]

■ 2. In § 520.1195, in paragraph (b)(1) remove “No. 050604” and add in its place “Nos. 050604 and 054925”; and in paragraph (b)(2) remove “054925, 058829,” and add in its place “058829”.

Dated: June 22, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. E6–10444 Filed 7–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

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 an abbreviated new animal drug application (ANADA) filed by Vétoquinol NA, Inc. The ANADA provides for use of oxytetracycline soluble powder to prepare medicated drinking water for the treatment of various bacterial diseases of livestock.

DATES: This rule is effective July 5, 2006.

FOR FURTHER INFORMATION CONTACT:

Daniel A. Benz, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: daniel.benz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Vétoquinol NA, Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada J5T 3S5, filed a supplement to ANADA 200–305 that provides for use of Oxytetracycline HCl Soluble Powder to prepare medicated drinking water for the treatment of various bacterial diseases of livestock. Vétoquinol NA, Inc.’s Oxytetracycline HCl Soluble Powder is approved as a generic copy of Alpharma, Inc.’s OXY–TET (oxytetracycline hydrochloride) Soluble approved under NADA 130–435. The ANADA is approved as of June 2, 2006, and the regulations are amended in 21 CFR 520.1660d to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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(a)(1) 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 Part 520

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 520 is 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. Amend § 520.1660d as follows:

■ a. Revise the section heading;

■ b. In paragraphs (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), (d)(1)(ii)(C)(3), and (d)(1)(iii)(C), remove “and 061133” and add in its place “059320, and 061133”; and

■ c. Add paragraphs (a)(10) and (b)(8).

The revisions read as follows:

§ 520.1660d Oxytetracycline powder.

(a) * * *

(10) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.74 oz; pails: 5 lb).

(b) * * *

(8) No. 059320 for use of OTC concentration in paragraph (a)(10) of this section in chickens, turkeys, and swine as in paragraph (d) of this section.

* * * * *

Dated: June 22, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–10445 Filed 7–3–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Griseofulvin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.