grapefruit, tangerines, and tangelos prior to Christmas Day will result in market supplies in excess of market needs. An accumulation of excessive quantities of any variety of citrus fruit in the markets during the period immediately prior to and following Christmas contributes to unstable marketing conditions. It is the Department's view that, absent a four and one-quarter day shipping holiday, excessive shipments of the specified fruits would occur, causing an accumulation of these varieties of fruit in the market prior to and during the post-holiday period, a period in which there is a drop in consumer demand. Hence the curtailment of orange, grapefruit, tangerine and tangelo shipments as hereinafter specified in this final rule would contribute to a better-managed supply situation and in turn to the establishment of orderly marketing.

After consideration of all relevant information, including the recommendation and information submitted by the committee, and the information received from those in opposition, it is hereby found that the establishment of the shipping holiday, as provided in this final rule, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is further found that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice and to engage in public rulemaking procedure, and that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** for the following reasons. There is insufficient time between the date when information became available upon which this action is based and the effective date necessary to effectuate the declared purposes of the Act. Determination as to the need for, and extent of, the regulation in this action requires the development of the crop and the availability of information about market supplies and the demand for such citrus. A reasonable time is permitted, under the circumstances, for preparation for effective date. The recommendation and supporting information for such regulation were promptly submitted to the Department after a meeting of the committee open to the public. This was after notice to growers, shippers, and interested persons had been given, where growers, shippers, and other interested persons were afforded an opportunity to submit information and views of the committee. Information regarding specifications of this action has been provided to shippers, and the regulation is identical with the recommendations of the committee. Compliance with the regulation will not require any special preparation by the persons subject thereto which cannot be completed on or before the effective date. Finally, in past seasons, some confusion has existed as to whether a shipping holiday was or was not in effect. Issuance of this final rule at the earliest possible date will eliminate any confusion among the trade. Accordingly, the citrus industry will be given adequate time to arrange shipping schedules in consideration of the shipping holiday.

List of Subjects in 7 CFR Part 905

Marketing agreements and orders, Florida, Grapefruit, Oranges, Tangelos, Tangerines.

PART 905—[AMENDED]

1. The authority citation for 7 CFR Part 905 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. The provisions of § 905.306 are amended by revising paragraph (d) to read as follows:

§ 905.306 Orange, Grapefruit, Tangerine, and Tangelo Regulation 6, Amendment 42.

* * * * *

(d) Notwithstanding the provisions of Table I in paragraph (a) of this section, during the period beginning at 6:00 p.m., E.S.T., December 24, 1986, and ending at midnight, E.S.T., December 28, 1986, no handler shall ship between the production area and any point outside thereof in the continental U.S., Canada, or Mexico, any oranges, grapefruit, tangerines, or tangelos, of the varieties, specified in paragraph (a) Table I of this section, grown in the production area.

* * * * *

Dated: December 2, 1986.

Joseph A. Gribbin,

Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 86–27744 Filed 12–9–86; 8:45 am]

BILLING CODE 3410–02–M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 211

[Release Nos. 33–6679; 34–23854; FR–28; AAER–120]

Accounting for Loan Losses by Registrants Engaged in Lending Activities

AGENCY: Securities and Exchange Commission.

ACTION: Interpretation.

SUMMARY: This release expresses the Commission's views regarding certain matters affecting reported amounts of loan losses. These matters include: (a) The need for procedural discipline in determining amounts of loan losses to be reported; (b) the requirement to account for loan collateral as repossessed, whether it is repossessed formally or substantively; and (c) valuation of loan collateral that is formally or substantively repossessed.

FOR FURTHER INFORMATION CONTACT: Wayne G. Pentrack, Office of the Chief Accountant (202–272–2130), or Howard P. Hodges, Jr., Division of Corporation Finance (202–272–2553), Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission has determined that certain financial reporting practices of some registrants engaged in lending activities may result in misstatement of their loan losses.

The Commission is publishing its views on these practices so that they may be appropriately considered by registrants and auditors in meeting their responsibilities under the Federal securities laws. The practices regarding substantive repossessions of collateral and valuation of formally or substantively repossessed collateral are described in the context of circumstances illustrative of actual circumstances noted in investigative and other activities of the Commission's staff.

II. Procedural Discipline in Determining the Allowance and Provision for Loan Losses To Be Reported

Certain registrants have appeared to lack adequate documentation of procedures for: (a) Performing periodic detailed reviews to identify risks inherent in their loan portfolios (e.g., problem loans, potential problem loans, loans to be charged off) and assessing the overall quality (i.e., collectibility) of their portfolios; and (b) determining amounts of allowances and provisions for loan losses to be reported based on the results of the detailed reviews. Neither the detailed reviews nor the determinations of amounts to be reported as loan losses appeared to have been conducted in an appropriately systematic manner by those registrants. Periodic fluctuations in their reported loan losses appeared, generally, to have no logical relationship

to the results of their periodic detailed loan reviews.

Arriving at an appropriate reported allowance for loan losses necessarily involves a high degree of management judgment. Because the allowance and the related provision for loan losses are key elements of financial statements of registrants engaged in lending activities, it is critical that those judgments be exercised in a disciplined manner that is based on and reflective of adequate detailed analyses of the loan portfolio.

Accordingly, in conducting an investigation, the Commission's staff normally would expect to find that the books and records of registrants engaged in lending activities include documentation of: (a) Systematic methodology to be employed each period in determining the amount of loan losses to be reported, and (b) rationale supporting each period's determination that the amounts reported were adequate. The systematic methodology to be employed each period would be documented not so that reported amounts will be the result of routine mathematical exercise, but to help ensure that all relevant matters affecting loan collectibility will consistently be identified in the detailed review process, and that the findings of the detailed review will be considered in an appropriately disciplined manner by persons exercising judgment in determining the amounts to be reported. The specific rationale upon which the amount actually reported in each individual period is based—i.e., the bridge between the findings of the detailed review and the amount actually reported in each period—would be documented to help ensure the adequacy of the reported amount, to improve auditability, and to serve as a benchmark for exercise of prudent judgment in future periods.

III. Substantive Repossessions of Collateral

Assume that a registrant had extended loans to oil and gas producers, who had pledged certain producing properties as collateral for those loans. The fair value of the collateral was in excess of the loan balances at the time the loans were extended. However, as energy prices declined, the borrowers determined that their further exploitation of the collateral would not be sufficiently rewarding and defaulted on the loans. The registratnt sought negotiations to restructure the loans by extending the repayment schedule (knowing, of course, that a restructuring would not affect the amount or timing of cash flow that could be generated by operation of the collateral) while the borrowers retained legal title to the collateral.

Further assume that, at the time of default, the properties were still thought to be capable of generating positive cash flow, but at a rate much lower than originally anticipated for various reasons (e.g., the energy price decline and/or downward revisions of reserve quantity estimates). Engineering estimates prepared at the time of default, based on long-tem assumptions regarding energy prices, projected that the undiscounted net cash flow from continued operation of the collateral would recover the carrying amount of the loans over a period much longer than originally anticipated (e.g., thirty to forty years). The present value of that projected cash flow and, thus, the fair value of the collateral, was significantly less than the carrying value of the loans.

The Commission has become aware that, in circumstances such as those described above, some registrants may believe that no loss need be recognized on the loans, on the basis that there is always the option of modifying the terms of the loans to call for repayments which, on an undiscounted basis, would eventually recover the carrying value of the loans. Should that option be exercised, some have argued, no loss recognition would be required under the provisions of paragraphs 30 and 31 of Statement of Financial Accounting Standards No. 15 ("FAS 15").[1] Essentially, this argument is founded on the premise that if collateral is not formally repossessed, there is no requirement to recognize losses based on the collateral's fair value.

Reliance upon accounting standards applicable to restructurings of debt through modification of terms (e.g., changes in maturities and/or interest rates) will often be inappropriate in these circumstances. The lenders may be more exposed to the risks of ownership of the collateral and more in a position to benefit from any recovery in its fair value than the borrowers. Thus, even if the maturity and/or interest rate terms of the loans would be formally modified to allow for repayment over many years, such a troubled debt restructuring may, in substance, constitute a repossession of the collateral. Paragraph 34 of FAS 15 states that a troubled debt restructuring that is in substance a repossession requires loss recognition based on the excess of the recorded investment in the loan over the fair value of the collateral that is, in substance, repossessed.

A registrant cannot avoid the fair value accounting required by FAS 15 when collateral is repossessed, simply by avoiding a formal repossession. That concept is clearly expressed in paragraphs 34 and 84 of FAS 15, although it is expressed there in the context of a formal debt restructuring. Collateral that has substantively been repossessed should be accounted for in the same manner as collateral that has been formally repossessed, irrespective of whether the related loan is formally restructured. To encourage more consistent applications of accounting principles in this area, the following discussion sets forth criteria which generally should be considered in determining whether substantive repossession accounting is appropriate, and the rationale for those criteria.

A. Applicability

The criteria listed below should be applied to any collateralized loan [2] which, because of the surrounding facts and circumstances, represents a loss contingency for the creditor and is being evaluated for possible accrual of the loss contingency,[3] irrespective of whether it has been restructured formally by modification of terms.

B. Criteria

Collateral generally should be considered repossessed in substance and accounted for at its fair value, consistent with repossession accounting as described in paragraphs 28 and 29 of FAS 15, when:

1. The debtor has little or no equity in the collateral, considering the current fair value of the collateral; *and*

2. Proceeds for repayment of the loan can be expected to come only from the operation or sale of the collateral; *and*

3. The debtor has either:

(a) Formally or effectively abandoned control of the collateral to the creditor, *or*

(b) Retained control of the collateral but, because of the current financial condition of the debtor, or the economic prospects for the debtor and/or the

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[1] Statement of Financial Accounting Standards No. 15: *Accounting by Debtors and Creditors for Troubled Debt Restructurings* (Stamford, CT: FASB, 1977).

[2] A collateralized loan, for this purpose, is any loan extended by a creditor in whole or in part on the basis of a security interest in assets or other property (tangible or intangible) of the debtor or a third-party guarantor. It would not include, for example, unsecured loans or loans to governmental agencies secured by tax-supported revenue streams.

[3] The accounting requirements for accrual of loss contingencies are specified in paragraphs 8 (generally) and 22–23 (specifically in the context of receivables) of Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies* (Stamford, CT: FASB, 1975).

collateral in the foreseeable future, it is doubtful that the debtor will be able to rebuild equity in the collateral or otherwise repay the loan in the foreseeable future.

C. Discussion of Criteria

The first two criteria are analogous to certain criteria contained in the February 1986 AICPA Notice to Practitioners ("the Notice") regarding accounting for real estate acquisition, development and construction ("ADC") arrangements,[4] and are intended to be used here in the same spirit as used in the Notice. Pursuant to the Notice, those criteria are used by a financial institution in determining, at the time it finances an ADC project, whether the financing is in substance an investment rather than a loan based on whether the risks and rewards of the project rest first and foremost with the financial institution. In assessing whether substantive repossession accounting is appropriate, these criteria should be used to identify situations where the primary risks and rewards of collateral ownership have passed from the debtor to the lender.

The third criterion recognizes that ongoing debtor commitment is a factor in assessing whether collateral has in substance been repossessed. It is intended to allow that repossession accounting may not be necessary when the debtor continues good faith efforts toward successful operation of the collateral and eventual repayment of the loan; provided, however, that the creditor can demonstrate a reasonable basis for concluding that the loan will be ultimately collectible.

The spirit of each of the above criteria should be carefully applied in the context of the facts and circumstances surrounding specific loans being evaluated. This is of particular importance with respect to criterion 3(b). For example, when using forecasts to assess a debtor's ability to improve its financial condition or future economic prospects for collateral, registrants and their auditors should be mindful that it is difficult to establish reasonable reliability of assumptions as to future events for purposes of overcoming doubts. Because assumptions underlying forecasts become less reliable as they look farther into the future, the word "foreseeable" in criterion 3(b) establishes that any relied-upon assumptions must be expected to be attainable within a reasonable manageable future period.

IV. Valuation of Formally or Substantively Repossessed Collateral

Assume that a registrant had extended loans to oil and gas drilling companies, with the borrowers' drilling rigs serving as collateral. The fair value of the rigs was in excess of the amounts loaned at the time the loans were granted. However, as energy prices declined, the borrowers were unable to profitably operate the rigs and defaulted on the loans. The registrant repossessed the rigs and placed them in storage while considering whether to sell them immediately or to hold them in anticipation of a future recovery in energy prices.

Assume further that the only active market in which rigs similar to those repossessed by the registrant were then being sold was an auction market where rigs were being purchased for speculative purpose (i.e., by persons who hoped to profit by holding rigs in anticipation of a future recovery in energy prices) or for parts, at prices substantially lower than the rigs' historical prices. The registrant elected to hold the rigs rather than sell them at their then-current market values. The registrant requested and obtained from a petroleum engineering company a projection of energy price and rig utilization levels several years hence and an estimate of the cost to store and maintain the rigs for that number of years, and derived from that data an estimate of the rigs' value which was substantially higher than their then-current market value.

The Commission has become aware that some registrants, in circumstances such as these, may believe that it would be acceptable to value the repossessed rigs at the derived amount, rather than at current market value, for financial reporting purposes.

FAS 15 requires that the accounting for collateral that is formally or substantively repossessed in satisfaction of a loan receivable is to be based on the collateral's fair value, and that fair value for this purpose is equal to market value if an active market for the collateral exists.[5] Registrants will, of course, opt for the strategies they expect will maximize returns or minimize losses. However, where fair value accounting is required by generally accepted accounting principles ("GAAP"), the mere adoption of strategies (such as a hold-for-the-future strategy that is based on expectations of future price increases, or a strategy of operating the repossessed collateral for one's own behalf) cannot justify use of derived accounting valuations that portray results of operations more favorably than would use of current values in active markets.

The Commission will presume that active markets reflect objective measures of current fair values, determined by the beliefs of reasonably informed persons regarding the present and future economic utility of the items being traded and the risks associated therewith. Thus, without independent and objective support for derived valuations that can be demonstrated to more appropriately reflect fair value in particular sets of circumstances, derived valuations exceeding current values in active markets should not be used in cases where fair value accounting is required by GAAP.[6]

V. Codification Update

The "Codification of Financial Reporting Policies" announced in Financial Reporting Release No. 1 (April 15, 1982) is updated to:

1. Add a new § 401.09, entitled "Accounting for Loan Losses by Registrants Engaged in Lending Activities".

2. Include in § 401.09 the sections of this Release entitled "Background", "Procedural Discipline in Determining the Allowance and Provision for Loan Losses to be Reported", "Substantive Repossessions of Collateral", and "Valuation of Formally or Substantively Repossessed Collateral"; indentifed respectively as subsections (a), (b), (c), and (d) of § 401.09.

The Codification is a separate publication of the Commission. It will not be published in the **Federal Register**/Code of Federal Regulations System.

PART 211—[AMENDED]

Commission Action: Subpart A of 17 CFR Part 211 is amended by adding thereto reference to this Release [FRR No. 28].

[4] *Notice to Practitioners—ADC Arrangements* (New York: AICPA, 1986).

[5] If no active market exists for a particular item, FAS 15 requires the fair value of the item to be estimated based on selling prices of similar items in active markets or, if there are no active markets for similar items, by discounting the cash flows expected to be generated by the item at a rate commensurate with the risk involved.

[6] Computations of gain or loss on repossession of collateral must consider not only the collateral's fair value, but also whether the registrant's security interest in the collateral is perfected and, if so, the priority of the registrant's claim.

By the Commission.
Jonathan G. Katz,
Secretary.
December 1, 1986.

[FR Doc. 86-27739 Filed 12-9-86; 8:45 am]
BILLING CODE 8010-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Ivermectin Paste

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

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Merck Sharp & Dohme Research Laboratories providing for use of Ivomec® (ivermectin) paste for treating and controlling certain parasites in cattle.

EFFECTIVE DATE: December 10, 1986.

FOR FURTHER INFORMATION CONTACT: Adriano R. Gabuten, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: Merck Sharp & Dohme Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, has filed a new animal drug application (NADA 137-006) for Ivomec® (ivermectin) Cattle Paste 0.153%. The NADA provides for use of the drug for the control and treatment of certain roundworm, lungworm, grub, and lice infestations in cattle. The NADA is approved and the regulations for ivermectin paste (21 CFR 520.1192 (a) and (c)) are amended by revising paragraph (a), by redesignating paragraph (c)(1) as paragraph (c)(1)(i) and revising it, by redesignating paragraphs (c) (2) and (3) as paragraphs (c)(1) (ii) and (iii), and by adding new paragraph (c)(2) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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 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, Part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 520 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. Section 520.1192 is amended by revising paragraph (a), by redesignating paragraph (c)(1) as paragraph (c)(1)(i) and revising it, by redesignating paragraphs (c) (2) and (3) as paragraphs (c)(1) (ii) and (iii), and by adding new paragraph (c)(2) to read as follows:

§ 520.1192 Ivermectin paste.

(a) *Specifications*—(1) *Horses.* Paste contains 1.87 percent ivermectin.

(2) *Cattle.* Paste contains 0.153 percent ivermectin.

* * * * *

(c) *Conditions of use*—(1) Horses—(i) *Amount.* 200 micrograms per kilogram (91 micrograms per pound) of body weight.

* * * * *

(2) *Cattle*—(i) *Amount.* 23 milligrams per 250 pounds of body weight.

(ii) *Indications for use.* It is used in cattle for the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (*Ostertagia ostertagi* (including inhibited forms), *O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, Nematodirus helvetianus, Bunostomum phlebotomum, Strongyloides papillosus* (adults only), *Oesophagostomum radiatum, Trichuris ovis* (adults only)); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (first, second, and third instars) (*Hypoderma bovis, H. lineatum*); and sucking lice (*Linognathus vituli, Haematopinus eurysternus*).

(iii) *Limitations.* For oral use only. Do not treat cattle within 24 days of slaughter. Because withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Dated: December 4, 1986.
Gerald B. Guest,
Director, Center for Veterinary Medicine.

[FR Doc. 86-27671 Filed 12-9-86; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Tripelennamine Hydrochloride Injection

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

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by codifying an approved new animal drug application (NADA) filed by Solvay Veterinary, Inc. The application provides for safe and effective use of tripelennamine hydrochloride injection as an antihistamine in horses, cattle, dogs, and cats. Codification of this application reflects compliance with the conclusions of the National Academy of Sciences/National Research Council (NAS/NRC) (academy) evaluation of the product. This document also amends the regulations to indicate those conditions of use for which applications for approval of identical products need not include certain types of effectiveness data. These conditions of use were classified as effective as a result of the NAS/NRC review. In lieu of certain effectiveness data, approval may require submission of bioequivalence or similar data.

EFFECTIVE DATE: December 10, 1986.

FOR FURTHER INFORMATION CONTACT: Donald A. Gable, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: Solvay Veterinary, Inc., P.O. Box 7348, Princeton, NJ 08540, filed NADA 6-417 that provides for use of tripelennamine hydrochloride injection as an antihistamine in horses, cattle, dogs, and cats. NADA 6-417 was originally approved on January 29, 1948. The drug was the subject of a NAS/NRC report which was published in the **Federal Register** of August 21, 1970 (DESI 6417V,

35 FR 13402). The report covered use of tripelennamine hydrochloride tablets and an injectable product containing 20 milligrams of tripelennamine hydrochloride per milliliter of aqueous solution.

The academy evaluated the drug as probably effective for use in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease in horses, cattle, sheep, swine, goats, dogs, and cats. The academy stated: (1) The rationale underlying the use of the preparation as a central nervous system stimulant for the "downer cow" syndrome is questioned; consequently, this claim should be deleted trom the label; (2) references to specific diseases should be deleted from the label unless they can be properly substantiated; (3) the documentation of efficacy is inadequate in that it is based primarily upon clinical reports and no controlled data are available in the veterinary medical literature; (4) evidence must be provided to establish that the tablets disintegrate in the gastrointestinal tract of the medicated species to produce the desired therapeutic effect; (5) the labeling should include information on side effects such as: (a) depression of the central nervous system and the incoordination that may occur when the drug is used at therapeutic dose levels; (b) disturbances in gastrointestinal functions that may occur; and (c) the fact that overdosage may give rise to excitement, ataxia, and convulsions; and (6) it is suggested that the labeling limit the indications for use to conditions in which antihistaminic therapy may be expected to lead to the alleviation of some signs of disease. Efficacy is not well established except in the case of exposure to an antigen to which the animal has a preexisting sensitivity. The sedative and antiemetic actions of antihistaminic drugs on the central nervous system may have prophylactic or therapeutic value in selected situations.

The Food and Drug Administration concurred with the academy's findings.

The NAS/NRC evaluation of the drug is concerned only with the effectiveness and safety of the drug for the treated animal and does not take into account safety of food use of drug-treated animals.

The firm submitted a supplemental NADA which brought the application into compliance with the conclusions of the review. The firm indicated that the tablet (bolus) product would be deleted, and the firm only wanted to update the NADA for use of the injectable product in dogs, cats, horses, and cattle. The regulations are amended by adding a new § 522.2615 (21 CFR 522.2615) to reflect the conditions of approval and to indicate those conditions of use which are NAS/NRC approved.

NADA's that pertain to identical products and reflect those conditions of use as set forth in this regulation do not require efficacy data as specified by § 514.1(b)(8)(ii) or § 514.111(a)(5)(ii)(*a*)(*4*) (21 CFR 514.1(b)(8)(ii) or 514.111(a)(5)(ii)(*a*)(*4*)) of the animal drug regulations. In lieu of such data, approval may require bioequivalency or similar data as suggested in the guideline for submitting NADA's for NAS/NRC-reviewed generic drugs. The guideline is available from the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

This document does not involve reevaluation or reaffirmation of the underlying human safety data. Human safety data will be evaluated and affirmed in accordance with the scheduled priorities of the agency.

The agency 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, Part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

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

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. New § 522.2615 is added to Part 522 to read as follows:

§ 522.2615 Tripelennamine hydrochloride injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 20 milligrams of tripelennamine hydrochloride.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs, cats, and horses.* For intramuscular use only at a dose of 0.5 milligram per pound of body weight.

(ii) *Cattle.* Administer intravenously or intramuscularly at a dose of 0.5 milligram per pound of body weight.

(2) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

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

(d) *NAS/NRC status.* These 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 data.

Dated: December 4, 1986.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 86–27670 Filed 12–9–86; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 546

Tetracycline Antibiotic Drugs for Animal Use; Tetracycline Soluble Powder

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Medico Industries, Inc., providing for use of tetracycline hydrochloride soluble powder in chickens and turkeys. Approval exists for use of the drug in calves and swine. The supplemental NADA provides for (1) control of chronic respiratory disease, air sac infections, and infectious synovitis in chickens; and (2) control of infectious synovitis and bluecomb in turkeys.

EFFECTIVE DATE: December 10, 1986.

FOR FURTHER INFORMATION CONTACT: Charles E. Haines, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3410.

SUPPLEMENTARY INFORMATION: Medico Industries, Inc., Elkan Estates, P.O. Box 338, Elwood, KS 66024, has filed a supplement to NADA 65–496 for use of Tetracycline Hydrochloride Soluble Powder-324™ in the drinking water of chickens and turkeys in addition to its currently approved use in the drinking water of calves and swine. Drinking water containing 1,000 milligrams of tetracycline hydrochloride activity per gallon is administered to chickens and turkeys to provide 25 milligrams of drug