(e) A periodic plan, in which instance the bank shall mail or otherwise furnish to the customer, as promptly as possible after each transaction, a written statement showing (1) the funds and securities in the custody or possession of the bank, (2) all service charges and commissions paid by the customer in connection with the transaction, and (3) all other debits and credits of the customer's account involved in the transaction; *provided* that upon the written request of the customer the bank shall furnish the information described in § 344.4, *except* that any such information relating to remuneration paid in connection with the transaction need not be provided to the customer when paid by a source other than the customer. The bank may charge a reasonable fee for providing the information described in § 344.4.

§ 344.6 Securities Trading Policies and Procedures.

Every bank effecting securities transactions for customers shall establish written policies and procedures providing:

(a) assignment of responsibility for supervision of all officers or employees who (1) transmit orders to, or place orders with broker/dealers, or (2) execute transactions in securities for customers;

(b) for the fair and equitable allocation of securities and prices to accounts when orders for the same security are received at approximately the same time and are placed for execution either individually or in combination;

(c) where applicable, and where permissible under local law, for the crossing of buy and sell orders on a fair and equitable basis to the parties to the transaction; and

(d) that bank officers and employees who make investment recommendations or decisions for the accounts of customers, who participate in the determination of such recommendations or decisions, or who, in connection with their duties, obtain information concerning which securities are being purchased or sold or recommended for such action, must report to the bank, within ten days after the end of the calendar quarter, all securities transactions made by them or on their behalf, either at the bank or elsewhere, in which they have a beneficial interest. The report shall identify the securities purchased or sold and indicate the dates of the transactions and whether the transactions were purchases or sales. Excluded from this requirement are transactions for the benefit of the officer or employee over which the officer or employee has no direct or indirect influence or control, transactions in mutual fund shares, and transactions involving in the aggregate $10,000 or less in principal amount during the quarter.

§ 344.7 Exceptions.

(a) The requirements of §§ 344.3(b) through 344.3(d) shall not apply to banks having an average of less than 200 securities transactions per calendar year for customers over the prior three-calendar-year period;

(b) Activities of a bank that are subject to regulations promulgated by the Municipal Securities Rulemaking Board shall not be subject to the requirements of this Part; and

(c) Activities of foreign branches of a bank shall not be subject to the requirements of this Part.

By order of the Board of Directors, July 16, 1979.

Federal Deposit Insurance Corporation

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 79-22684 Filed 7-23-79; 8:45 am]

BILLING CODE 6714-01-M

FEDERAL TRADE COMMISSION

16 CFR Part 13

[Docket C-2972]

Arnaudville Industries, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Final order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, among other things, requires an Arnaudville, La. manufacturer and seller of mobile homes to cease improperly designating its warranties; and failing to include in its warranties all the information required by the Disclosure Rule, 16 CFR 701 (1977). The order further requires that purchasers of firm's products manufactured after July 4, 1975, whose warranties are still in effect, be informed, as prescribed, of their legal rights and the firm's obligations under warranties.

DATES: Complaint and order issued June 21, 1979.*

FOR FURTHER INFORMATION CONTACT: ETC/PR, Barbara Rowan, Washington, D.C. 20580. (202) 523-1642.

*Copies of the Complaint and Decision and Order are filed with the original document.

SUPPLEMENTARY INFORMATION: On Monday, April 16, 1979, there was published in the Federal Register, 44 FR 22488, a proposed consent agreement with analysis In the Matter of Arnaudville Industries, Inc., a corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR 13, are as follows: Subpart—Advertising Falsely or Misleadingly: § 13.70 Fictitious or misleading guarantees; § 13.73 Formal regulatory and statutory requirements; § 13.205 Scientific or other relevant facts; § 13.260 Terms and conditions. Subpart—Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements; 13.533-20 Disclosures; 13.533-37 Formal regulatory and/or statutory requirements; 13.533-45 Maintain records; 13.533-75 Warranties. Subpart—Misrepresenting Oneself and Goods—Goods: § 13.1623 Formal regulatory and statutory requirements; § 13.1647 Guarantees; § 13.1760 Terms and conditions. Subpart—Neglecting, Unfairly or Deceptively, To Make Material Disclosure: § 13.1852 Formal regulatory and statutory requirements; § 13.1895 Scientific or other relevant facts; § 13.1905 Terms and conditions.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46; interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 110(b), 88 Stat. 2190; 15 U.S.C. 2310)

Carol M. Thomas,

Secretary.

[FR Doc. 79-22811 Filed 7-23-79; 8:45 am]

BILLING CODE 6750-01-M

---

16 CFR Part 13

[Docket C-2971]

Fedders Corp.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Final order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent

agreement requires an Edison, N.J. manufacturer and distributor of various products, including split system heat pumps, to offer, without charge, a replacement defrost cycle switch to all current owners of split system heat pumps manufactured by Fedders between November, 1975 and June 1, 1978; to extend a full warranty on the sealed system of the heat pump until May 1, 1980 to those purchasers who elect installation of the new defrost switch; and to reimburse all past or current owners of the affected heat pumps for any repair to the sealed system of the unit for which the owner has paid. The firm is required to mail notices to current and past owners of the affected heat pumps to let them know about the remedial program, and advertise the program in national magazines if a sufficient number of owners cannot be reached by letters.

DATES: Complaint and order issued June 14, 1979.*

FOR FURTHER INFORMATION CONTACT: FTC/PE, Robert S. Blacher, Washington, D.C. 20580. (202) 724–1507.

SUPPLEMENTARY INFORMATION: On Monday, February 26, 1979, there was published in the **Federal Register**, 44 FR 10985, a proposed consent agreement with analysis In the Matter of Fedders Corporation, a corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of order.

Comments were filed and considered by the Commission. The Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR 13, are as follows: Subpart-Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements; 13.533–20 Disclosures; 13.533–55 Refunds, rebates and/or credits; 13.533–75 Warranties.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Carol M. Thomas,

Secretary.

[FR Doc. 79-22809 Filed 7-23-79; 8:45 am]

BILLING CODE 6750-01-M

* Copies of the Complaint and Decision and Order are filed with the original document.

16 CFR Part 13

[Docket C-2973]

Madison Mobile-Modular Homes, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Final order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, among other things, requires an Ontario, Calif. manufacturer and seller of mobile homes to cease failing to properly designate its written warranties; disclose in its warranties all the information required by the Disclosure Rule, 16 CFR 701 (1977); and note in its warranty registration cards that warranty coverage or performance is not conditioned on the return of the cards. The firm is further required to notify purchasers of its mobile homes manufactured after July 4, 1975 of their implied warranty rights; and make available to these consumers all the relief provided under applicable state laws. Additionally, the order restrains the firm for four years from raising any defenses relating to the disclaimer of implied warranties in suits brought by affected purchasers.

DATES: Complaint and order issued June 21, 1979.*

FOR FURTHER INFORMATION CONTACT: FTC/PR, Barbara Rowan, Washington, D.C., 20580. (202) 523–1642.

SUPPLEMENTARY INFORMATION: On Monday, April 16, 1979, there was published in the **Federal Register**, 44 FR 22491, a proposed consent agreement with analysis In the Matter of Madison Mobile-Modular Homes, Inc., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR 13, are as follows: Subpart-Advertising Falsely or Misleadingly: § 13.70 Fictitious or misleading guarantees; § 13.73 Formal regulatory and statutory requirements; § 13.205 Scientific or other relevant facts; § 13.260 Terms and conditions. Subpart-Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements; 13.533–20 Disclosures; 13.533–37 Formal regulatory and/or statutory requirements; 13.533–45 Maintain records; 13.533–75 Warranties. Subpart-Misrepresenting Oneself and Goods—Goods: § 13.1623 Formal regulatory and statutory requirements; § 13.1647 Guarantees; § 13.1760 Terms and conditions. Subpart-Neglecting, Unfairly or Deceptively, To Make Material Disclosure: § 13.1852 Formal regulatory and statutory requirements: § 13.1895 Scientific or other relevant facts; § 13.1905 Terms and conditions.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46; interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 110(b), 88 Stat. 2190; 15 U.S.C. 2310)

Carol M. Thomas,

Secretary.

[FR Doc. 79-22810 Filed 7-23-79; 8:45 am]

BILLING CODE 6750-01-M

* Copies of the Complaint and Decision and Order are filed with the original document.

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 249

[Release No. 34-15979]

Requests for Confidential Treatment of Information Filed by Institutional Investment Managers

Correction

In FR Doc. 79–20888 appearing at page 39386 in the issue for Friday, July 6, 1979, on page 39387, in the fifth line of paragraph d, delete the first "of".

BILLING CODE 1505-01-M

17 CFR Parts 270 and 274

Exemption of Acquisition of Securities During the Existence of Underwriting Syndicate; Revision of Rule and Amendment of Form

Correction

In FR Doc. 79–19199 appearing at page 36152 in the issue for Wednesday, June 20, 1979, on page 36153, second column, third line of the Footnote, remove the word "not".

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

20 CFR Part 416

[Reg. No. 16]

Supplemental Security Income (SSI) Program; Valuing Resources on the Basis of Equity and Increasing Maximum Values on Certain Excluded Resources

AGENCY: Social Security Administration, HEW.

ACTION: Final rule.

SUMMARY: These regulations change the way we evaluate resources under the Supplemental Security Income (SSI) program. Instead of evaluating property (other than an automobile) by its current market value we use its equity value, i.e., current market value less encumbrances. The regulations also increase the maximum value of household goods, personal effects and an automobile before these items are counted in determining whether persons meet the statutory resource limit. One automobile is excluded if it meets certain use requirements or to the extent that its current market value does not exceed $4,500, but any excess over $4,500 is counted. Any other automobile is counted at its equity value.

EFFECTIVE DATE: All of these regulations will be effective beginning with November 1, 1979. However, we are giving § 416.1218, *Exclusion of the automobile*, interim effect and providing an additional period for public comment because this section has been changed from the NPRM as a result of comments received. Any additional comments must be received on or before September 24, 1979.

ADDRESSES: Written comments may be submitted to the Commissioner of Social Security, Department of Health, Education, and Welfare, P.O. Box 1585, Baltimore, Maryland 21203.

FOR FURTHER INFORMATION CONTACT: Henry D. Lerner, Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235, telephone (301) 594-7414.

SUPPLEMENTAL INFORMATION:

Prior Publications

Under the Social Security Act, a person whose resources exceed $1,500 and a couple whose resources exceed $2,250 may not be eligible for SSI benefits. The Act further provides that in determining resources there shall be excluded "household goods, personal effects, and an automobile, to the extent that their total value does not exceed such amount as the Secretary determines to be reasonable."

In the past, SSA has evaluated these resources under the SSI program on the basis of current market value and SSA regulations currently reflect that policy. The Secretary reviewed the policy and on May 2, 1978, published a Notice of Proposed Rulemaking in the **Federal Register** (43 FR 18698) changing the basis of evaluating resources from current market value to equity value.

On April 28, 1978, a Notice of Proposed Rulemaking was published in the **Federal Register** (43 FR 18206) increasing the value of houshold goods and personal effects and an automobile that a person may have before they are counted toward the statutory resource limit. The excluded amount for household goods and personal effects was increased from $1,500 to $2,000, with any excess value counted toward the statutory resource limit. Similarly, the excluded amount for an automobile was increased from $1,200 to $2,000. These increases were proposed to allow for inflation.

Since both NPRMs amend the same sections of the regulations, the final rules are combined for publication at the same time.

Comments on Prior Publications

(1) Views were expressed by a welfare policy and law organization regarding SSA's rulemaking procedure. The commenter stated that past proposed rules have been given interim effect and suggested that we give equal treatment to these proposed rules.

The Administrative Procedure Act (APA) requires publication of an NPRM in the **Federal Register**. Although the statute makes an exception for matters relating to benefits, the Department of Health, Education, and Welfare has committed itself to observe the APA requirements on rulemaking even in its benefit programs. Under the APA we can make an exception to publishing an NPRM if it is impracticable, unnecessary, or contrary to public interest. We believe that the two prior NPRMs proposed important changes in policy and, therefore, an opportunity for public comment was useful.

(2) The welfare policy and law organization also stated that it believed the following published statement in the NPRM of May 2, 1978 was incorrect:

> However, regulations pertaining to resources for purposes of the aid to families with dependent children (AFDC) program permit each State to decide whether to use current market value or equity value in evaluating resources for AFDC.

We agreed that this statement was inaccurate and we deleted it through a correction notice published in the **Federal Register** on March 26, 1979 (44 FR 18053).

(3) Several commenters felt that there was inequity in the proposed rules to increase the maximum value of the automobile before it would be counted as a resource. They stated that people who own automobiles and homes appear to have an advantage over those who do not. These commenters suggested that the maximum value on household goods and personal effects should be raised for those people who do not own automobiles and homes.

The Social Security Act provides that the value of household goods, personal effects, and an automobile is to be excluded from resources to the extent that the Secretary determines to be reasonable. Current regulations and these regulations both provide for establishing limits on resources by category, that is, for household goods, and personal effects and for an automobile. For these categories, we have set limits which we consider consistent, with the purpose of the SSI program, to enable the aged, blind and disabled persons to meet their subsistence needs. We have not established limits for the value of a home since the law requires that the total value of a home is to be excluded from resources. We have also concluded that there are special circumstances which justify entirely excluding an automobile. For example, if the automobile is needed for employment or medical treatment or if it has been modified for use by a handicapped person, we will exclude it without regard to its value. Similarly, we exclude the total value of certain household goods and personal effects. For example, we totally exclude items that are necessary because of a person's physical condition and which are not used by others in the household.

We believe that the commenters' suggestion would not be consistent with the purpose of the SSI program. Increasing the value of an exclusion of one kind of resource simply because an exclusion for another kind of resource is not taken advantage of would permit a person to have more resources of a particular kind than the person would otherwise need for subsistence. Therefore, we are not adopting the commenters' suggested change.

(4) Several commenters suggested that the reasonable values of household

goods, personal effects, and the automobile be increased yearly to keep pace with inflation.

The purpose of updating the limits of household goods, personal effects, and the automobile in these regulations is an attempt to maintain these limits in the same relative position to the economy as they were at the start of the SSI program in January 1974. We intend to reassess the limits periodically in light of inflation (and any other pertinent factors). We will consider updating the limits if warranted on the basis of these reassessments.

(5) Several commenters felt that the proposed amounts of $2,000 for the reasonable values of household goods, personal effects, and the automobile are insufficient because the amounts were based on 1976 information and do not keep up with current inflation.

While the increase in values reflect increased prices only for the period from April 1972 to June 1976, as indicated, we will consider updating the dollar limits in the future to reflect inflation after June 1976.

(6) Other commenters asked whether the proposed amendments have retroactive or prospective effect. These amendments will have prospective effect. Both the program and administrative costs involved in making these rules retroactive would be extremely high. In order to identify persons affected by a change in rules, all cases which were disallowed for a particular factor of eligibility (e.g., excess resources) would have to be identified, contacted and screened out, or processed. These rules will be effective the first day of the month following the expiration of 90 days after publication in the **Federal Register** (For example, if the rules are published July 25, 1979, the effective date will be November 1, 1979.) Time is needed to prepare, print, and distribute instructions to 1,200 field offices where these regulations will be implemented.

(7) One commenter asked that a standard concerning automobiles which Congress has written into the Food Stamp Act of 1977 be applied to the SSI program. The commenter suggests we count the amount by which the market value of an automobile exceeds $4,500. We are modifying our policy to incorporate this suggestion. We will exclude one automobile, regardless of value, if it meets certain use requirements, or to the extent that its current market value does not exceed $4,500. If the current market value exceeds $4,500, the excess will be counted toward the person's (or couple's) resource limit. Any other automobile is counted toward the resource limit at its equity value (unless it may be excluded under other resource rules—see § 416.1224(d) regarding exclusion of an automobile that is essential for self-support).

Interim Effect for Policy on Valuing the Automobile

We have changed the policy in § 416.1218 for valuing an automobile from that proposed in the two previous NPRMs dated April 29, 1978 and May 2, 1978. However, we are not publishing this change as another NPRM because (1) we have already announced our intent to revise the rules for valuing an automobile in the two earlier NPRMs, and (2) the change we have made is in response to public comments.

All of these regulations, including the rule on the automobile in § 416.1218, will be effective beginning November 1, 1979. The rule on the automobile is being given interim effect because of the change in policy from that in the NPRMs. The public will have an opportunity to comment on this rule for a period of 60 days following publication of these regulations. After we evaluate any comments we receive, we will publish this policy as a final rule.

(Secs. 1102, 1613(a), 1614(f), and 1631 of the Social Security Act, as amended; 49 Stat. 647, as amended, 86 Stat. 1470, as amended, 86 Stat. 1471, and 86 Stat. 1475 (42 U.S.C. 1302, 1382b(a), 1382c(f), and 1383))

(Catalog of Federal Domestic Assistance Program No. 13.807, Supplemental Security Income Program.)

Dated: July 12, 1979.

Stanford G. Ross,

Commissioner of Social Security.

Approved: July 17, 1979.

Joseph A. Califano, Jr.,

Secretary of Health, Education, and Welfare.

Part 416 of Chapter III of Title 20 of the Code of Federal Regulations is amended as follows:

1. Section 416.1201 is amended by revising paragraphs (b) and (c) to read as follows:

§ 416.1201 Resources; general.

* * * * *

(b) *Liquid resources; defined.* Liquid resources are those assets that are in cash or are financial instruments which are convertible to cash. Liquid resources include cash on hand, cash in savings accounts or checking accounts, stocks, bonds, mutual fund shares, promissory notes, mortgages, and similar properties. Liquid resources, other than cash, are evaluated according to their equity value.

(c) *Nonliquid resources; defined.* (1) Nonliquid resources include all other properties. the term includes both real and personal property. Nonliquid resources are evaluated according to their equity value except as otherwise provided. (See § 416.1218 for treatment of automobiles.)

(2) For purposes of this Subpart L, the "equity value" of an item is defined as:

(i) The price that item can reasonably be expected to sell for on the open market in the particular geographic area involved; minus

(ii) Any encumbrances.

2. Paragraph (b) of § 416.1216 is revised to read as follows:

§ 416.1216 Exclusion of household goods and personal effects.

* * * * *

(b) *Limitation on household goods and personal effects.* In determining the resources of an individual (and spouse, if any), household goods and personal effects are excluded if their total equity value is $2,000 or less. If the total equity value of household goods and personal effects is in excess of $2,000, the excess is counted against the resource limitation.

* * * * *

3. In § 416.1218, paragraph (d) is revoked and paragraphs (b) and (c) are revised to read as follows:

§ 416.1218 Exclusion of the automobile.

* * * * *

(b) *Limitation on automobiles.* In determining the resources of an individual (and spouse, if any), automobiles are excluded or counted as follows:

(1) *Total exclusion.* One automobile is totally excluded regardless of its value if, for the individual or a member of the individual's household—

(i) It is necessary for employment;

(ii) It is necessary for the medical treatment of a specific or regular medical problem; or

(iii) It is modified for operation by or transportation of a handicapped person.

(2) *Exclusion to $4,500 of the market value.* If no automobile is excluded under paragraph (b)(1) of this section, one automobile is excluded from counting as a resource to the extent its current market value does not exceed $4,500. If the market value of the automobile exceeds $4,500, the excess is counted against the resource limit.

(3) *Other automobiles.* Any other automobiles are treated as nonliquid resources and counted to the extent of their equity value (see § 416.1201(c)) against the resource limit. However, see § 416.1224(d).

(c) *Current market value.* The "current market value" of an automobile is the average price an automobile of that particular year, make, model, and condition will sell for on the open market (to a private individual) in the particular geographic area involved.

[FR Doc. 79-22818 Filed 7-23-79; 8:45 am]

BILLING CODE 4110-07-M

Food and Drug Administration

21 CFR Part 520

[Docket No. 79N-0211]

Oral Dosage Form New Animal Drugs Not Subject to Certification: Sulfamethoxypyridazine Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the animal drug regulation for sulfamethoxypyridazine tablets 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 product. In lieu of certain efficacy data, approval may require submission of bioequivalence or similar data. An earlier **Federal Register** publication has reflected this product's compliance with the conclusions of the review.

EFFECTIVE DATE: July 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 this product was published in the **Federal Register** of October 17, 1969 (34 FR 16636). In that document, the Academy concluded, and Food and Drug Administration (FDA) concurred, that the product was probably effective for the treatment of bacterial infections in the genitourinary respiratory and gastrointestinal systems of dogs and cats.

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.

The Parke, Davis & Co., Joseph Campau Avenue at the River, Detroit, MI 48232, responded to the notice by submitting a supplemental NADA (12-821V) providing current information covering manufacturing and controls and revising the labeling for the safe and effective use of the product in treating infections in dogs and cats. A regulation was published in the **Federal Register** of September 21, 1971 (36 FR 18726) setting forth the conditions of approval of the supplemental NADA. The regulation reflecting this approval (21 CFR 135C.41, recodified 21 CFR 520.2300) 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 approvals 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), Part 520, is amended in § 520.2300 by adding after paragraph (d) (1), (2), and (3) the footnote reference "1" and by adding at the end of the section the footnote to read as follows:

§ 520.2300 Sulfamethoxypyridazine tablets.

* * * * *

(d) *Conditions of use.* (1) * * * [1]

(2) * * * [1]

(3) * * * [1]

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

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

[1] 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 information.

Dated: July 17, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79-22724 Filed 7-23-79; 8:45 am]

BILLING CODE 4110-03-M

---

21 CFR Part 520

[Docket No. 79N-0216]

Oral Dosage Form New Animal Drugs Not Subject to Certification; Promazine Hydrochloride

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the animal drug regulations for promazine hydrochloride 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 product. In lieu of certain efficacy data, approval may require submission of bioequivalence or similar data. An earlier **Federal Register** publication has reflected this product's compliance with the conclusions of the review.

EFFECTIVE DATE: July 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 this product 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 (FDA) concurred, that the product was probably effective as a tranquilizer 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.

Fort Dodge Laboratories, Fort Dodge, IA 50501, responded to the notice by submitting a supplemental NADA (12-656V) providing current information covering manufacturing and controls and revising the labeling for the safe