§929.60 and §929.48 shall be mailed to the committee office at Middleboro, Mass., or delivered to that office. If the report is mailed, it shall be deemed filed when postmarked.

(b) * * *

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.)

Effective date: August 15, 1978.

Signed at Washington, D.C., on: July 6, 1978.

P. R. "BOBBY" SMITH,
Assistant Secretary for Marketing Services.

[FR Doc. 78-19094 Filed 7-10-78; 8:45 am]

[3410-05]

CHAPTER XIV—COMMODITY CREDIT CORPORATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—LOANS, PURCHASES, AND OTHER OPERATIONS

PART 1464—TOBACCO

Subpart A—Tobacco Loan Program

1978 CROP GRADE LOAN RATES—FLUE-CURED TOBACCO

AGENCY: Commodity Credit Corporation, U.S. Department of Agriculture.

ACTION: Final rule.

SUMMARY: This rule establishes the schedule of grade loan rates which will apply to 1978 crop Flue-cured tobacco. The rule is needed to provide the statutory level of support for 1978-crop Flue-cured tobacco. Eligible Flue-cured tobacco may be delivered for price support at the specified rates.

EFFECTIVE DATE: July 11, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert P. Hieronymus, 202-447-6695.

SUPPLEMENTARY INFORMATION: On May 26, 1978, Commodity Credit Corporation (CCC) published in the FEDERAL REGISTER (43 FR 22727) a proposed schedule of grade loan rates for providing price support for 1978-crop Flue-cured tobacco at the statutory level of 121 cents per pound. The document invited interested parties to submit written views and recommendations to be received by June 26.

DISCUSSION OF COMMENTS

There were 15 responses received. Tobacco exporters and associations of tobacco exporters, 12 of the responses, expressed the view that the rates proposed for the grades in demand for export will cause exports to suffer because foreign importers will reduce the proportion of U.S. Flue-cured tobacco in their blends and increase the proportions of foreign grown tobacco obtainable at lower prices. None suggested, however, that the rates proposed for the grades in export demand are higher in relation to their value than the rates proposed for other grades.

The major thrust of the exporters' responses is that the statutory formula for determining the level of support should be modified so that in future years the level of support would be lower. This would allow grade loan rates for both upper and lower stalk grades to be established at levels to allow U.S. Flue-cured tobacco to better compete with foreign grown tobacco.

Two responses, one from a producer association and another from a State Department of Agriculture, recommended rates slightly lower than proposed for certain "P" and "N" grades for which there is little export demand and correspondingly higher rates on export grades. One farm organization expressed support for the grade loan rates as proposed.

After considering all the responses received, it has been decided to adopt the schedule of grade loan rates as proposed.

FINAL RULE

Accordingly, 7 CFR Part 1464 is amended by revising § 1464.16 to read as set forth below, effective for the 1978 crop of Flue-cured tobacco. The material previously appearing under § 1464.16 remains applicable to the crop to which it refers.

(Secs. 4, 5, 62 Stat. 1070, as amended (15 U.S.C. 714b, 714c), secs. 101, 106, 401, 403, 63 Stat. 1051, as amended (7 U.S.C. 1441, 1445, 1421, 1423).)

Based on an assessment of the environmental impacts of the proposed action, it has also been determined that an environmental impact statement need not be prepared since the proposals will have no significant effect on the quality of the human environment.

Signed at Washington, D.C., on July 5, 1978.

RAY FITZGERALD,
Executive Vice President, Commodity Credit Corporation.

§ 1462.16 1978 crop Flue-cured tobacco, types 11-14, loan schedule.[1]

[Dollars per 100 lb, farm sales weight]

Grade	Loan rate	Grade	Loan rate
A1F	156	B3KL	127
A1L	156	B4KL	123
B1L	146	B5KL	118
B2L	142	B6KL	112
B3L	139	B3KF	127
B4L	135	B4KF	123
B5L	131	B5KF	117
B6L	125	B6KF	112

[Dollars per 100 lb, farm sales weight]—Continued

Grade	Loan rate	Grade	Loan rate
B1F	146	B3KM	130
B2F	142	B4KM	127
B3F	139	B5KM	122
B4F	135	B6KM	114
B5F	131	B3KR	133
B6F	125	B4KR	129
B1FR	144	B5KR	124
B2FR	140	B4KV	118
B3FR	137	B5KV	113
B4FR	134	B6KV	107
B5FR	130	B4G	117
B6FR	124	B5G	113
B4R	123	B6G	107
B5R	116	B5GR	101
B3K	134	B4GK	114
B4K	130	B5GK	110
B5K	126	B6GK	105
B6K	119	B5GG	101
B3V	130	H3L	142
B4V	125	H4L	139
B5V	121	H5L	134
B3S	127	H6L	129
B4S	123	X3KM	124
B5S	117	X4KM	119
X1L	141	X4G	109
X2L	137	X5G	105
X3L	132	X4GK	109
X4L	127	P2L	113
X5L	118	P3L	107
X1F	141	P4L	99
X2F	137	P5L	93
X3F	132	P2F	113
X4F	127	P3F	107
X5F	118	P4F	99
X3V	123	P5F	93
X4V	118	P4G	89
X3S	123	P5G	83
X4KL	118	M4F	121
X4KF	118	M5F	116
X4KV	112	M4KR	115
X3KR	129	H1F	149
K4KR	124	H2F	145
H3F	142	C4KL	126
H4F	139	C4KM	127
H5F	134	C4KR	131
H6F	129	C4G	119
H4FR	136	C4GK	118
H5FR	131	M4KM	114
H6FR	126	M5KM	109
H4K	134	M4GK	108
H5K	129	M5GK	102
H6K	124	N1L	85
C1L	145	N1XL	90
C2L	142	N1K	97
C3L	139	N1R	88
C4L	136	N1GL	79
C5L	132		89
C1F	145	N1GF	89
C2F	142	N1GR	84
C3F	139	N1KV	88
C4F	136	N1GG	81
C5F	132	N1BO	80
C4V	127	N1XO	78
C4S	125	N1PO	74

[1] The loan rates listed are applicable to tied and untied Flue-cured tobacco which is: (1) Eligible tobacco as defined in the regulations, and (2) identified by a marketing card which does not bear the notation "Discount Variety-Limited Support." Rates for eligible tobacco identified by a marketing card which bears the notation "Discount Variety—Limited Support" are 50 percent of the loan rates listed plus fifty cents ($0.50) per 100 pounds. Any grade to which the special factor "sand" or "dirt" is added (denoting a moderate amount of sand or dirt in excess of normal) may be accepted at 90 percent, rounded to the nearest dollar, of the loan rate listed. Tobacco graded "W" (doubtful keeping order), "U" (unsound), "N2", "No-G", "No-G-F", "No G-F-sand", "No G-F-dirt", or "scrap" will not be accepted. Tobacco is eligible for advance only if consigned by the original producer. The cooperative association through which advances are made available is authorized to deduct 1 cent per pound to apply against overhead costs.

[FR Doc. 78-18996 Filed 7-10-78; 8:45 am]

[8010-01]

Title 17—Commodity and Securities Exchanges

CHAPTER II—SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-14910]

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

Filing and Disclosure Requirements Relating to Beneficial Ownership

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Commission is amending rules governing the disclosure of beneficial ownership and related requirements which took effect on May 30, 1978. These amendments relate to the application of such rules to a parent holding company and certain of its subsidiaries and to the beneficial ownership of pledged securities, including securities pledged to a broker-dealer in connection with margin account transactions. This action is taken as a result of certain interpretative questions concerning the rules and to clarify certain of the provisions of those rules.

EFFECTIVE DATE: July 11, 1978.

FOR FURTHER INFORMATION CONTACT:

John Granda, Office of Disclosure Policy and Proceedings, Division of Corporation Finance, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549, 202-755-1750.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission today announced the amendment of rules adopted in Securities Exchange Act Release No. 5925 (April 21, 1978) (43 FR 18484). The actions announced in that release were effective May 30, 1978 and pertain to amendments to rules and schedule 13D (17 CFR 240.13d-101), the adoption of new schedule 13G (17 CFR 240.13d-102) and the rescission of form 13D-5 (17 CFR 240.13d-102) relating to disclosure by certain beneficial owners of securities pursuant to section 13(d) of the Securities Exchange Act of 1934 ("Exchange Act") (15 U.S.C. 78a et seq., as amended by Pub. L. No. 94-29 (June 4, 1975) and Pub. L. No. 95-213 (December 19, 1977)). In that release, the Commission also amended certain of its forms and schedules under the Securities Act of 1933 ("Securities Act") (15 U.S.C. 77a et seq.) and under the Exchange Act to require issuers to disclose in a more uniform manner the percentage of their securities beneficially owned by certain persons.[1]

The amendments announced by the Commission herein involve revisions to rule 13d-1(b)(1)(ii)(G) and rule 13d-3(d)(3) concerning the filing obligation on schedules 13D and 13G, and the determination of beneficial ownership, respectively.

I. Background

A. Proposed Amendment to Rule 13d-1(b)(1)(ii)(G): Parent Holding Companies

Rule 13d-1(b), among other things, addresses the obligation of certain persons to file statements on schedule 13G and specifies certain conditions which if met enable reporting persons to use that short form rather than the long statement, schedule 13D. In general, those conditions include a requirement that a person filing on schedule 13G in satisfaction of a reporting obligation under section 13(d) be a specified type of institutional investor—such as a bank, insurance company, broker-dealer, investment company or employee benefit plan—or that the filing person have a specified relationship to such investors. Thus, the rule as adopted in release No. 33-5925 states that the persons eligible to use the short form include a parent holding company, provided certain conditions are met, including a condition by which holdings of less than 1 percent by a subsidiary which was not entitled to use the short form would not void the availability of the short form for the parent.[2]

As pointed out in release No. 33-5925, the basis for the 1-percent provision contained in the rule was that any requirement that all of the parent's subsidiaries owning the subject securities be one of the designated institutions, as a condition to the parent's use of schedule 13G, would effectively make the short form unavailable to most persons choosing to erect a holding company structure. This result would exist, for example, if a bank holding company had a single nonqualifying subsidiary which was the beneficial owner of securities of the subject class, with such ownership being attributed to the parent holding company. Since the Commission determined that a de minimus provision was consistent with the public interest, the 1-percent test was included in the rule, so long as the information called for by schedule 13D is furnished in the parent's schedule 13G with respect to the securities held by such subsidiary.

The amendments contained herein are intended to clarify and, in certain respects, relax the conditions of the provision. To confirm that holdings by the parent holding company itself are within the de minimus standard, the rule has been revised to indicate that the 1-percent provision applies to holdings of the parent holding company as well as to those of the non-qualifying subsidiaries. Also, to clarify the intention of the Commission in adopting the de minimus provision, it is stated that the 1-percent ceiling is the "aggregate" amount held directly by the parent and directly and indirectly by its non-qualifying subsidiaries.

The amendments also delete the requirement that schedule 13D-type information be furnished in the parent's schedule 13G. The Commission's intention concerning that requirement had been to preserve the parent's eligibility for the short form when minimal amounts of securities were held by non-qualifying subsidiaries, provided the subsidiaries' disclosure concerning only its holdings was comparable to that of persons required to report on schedule 13D. However, questions have arisen concerning the conceptual difficulty in segregating the non-qualifying subsidiary for purposes of preparing the schedule 13D information, and it has been pointed out that the scope of general instruction C and the items of schedule 13D would elicit disclosure concerning such a broad category of persons, holdings and transactions as to effectively undermine the intent of the de minimus provision. In view of the remaining conditions to the availability of schedule 13G, including the requirements that the acquisitions be in the ordinary course of business and not for the purpose nor with the effect of changing or influencing the control of the issuer, nor in connection with or as a participant in any transaction having such purpose or effect, the Commission believes it is appropriate to delete the requirement concerning the inclusion of schedule 13D-type information.

B. Proposed Amendment to Rule 13d-3(d)(3): Pledges

Rule 13d-3 defines the term "beneficial ownership" in terms of voting

[1] In Securities Exchange Act Release No. 14830 (June 5, 1978) (43 FR 25420) the Commission authorized the publication of staff interpretative views concerning the May 30, 1978 effective date and the application of the new rules to beneficial ownership holdings as of such date.

[2] As adopted in release No. 33-5925, rule 13d-1(b)(1)(ii)(G) provides:

(G) A parent holding company, provided that: (1) the schedule 13G is being used to report the indirect acquisition of the beneficial ownership of securities acquired by a subsidiary; and (2) such subsidiary is a person specified in rule 13d-1(b)(1)(ii) (§ 240.13d-1(b)(1)(ii)) except that the inclusion in the reported holdings of not more than 1 percent of a class beneficially owned by a subsidiary that is not so specified will not prevent the use of schedule 13G, so long as the information called for by schedule 13D is furnished in the parent's schedule 13G with respect to the securities of such subsidiary.

power or investment power and describes situations in which persons are deemed not to be the beneficial owner of securities. Rule 13d-3(d)(3) addresses the situation in which a person who is a pledgee of securities might, upon default, be deemed the beneficial owner of such securities. As explained in release No. 33-5925, the pledge provision was adopted largely in response to comments of institutional investors, particularly banks, who urged that they do not receive pledged securities for the purpose of exercising investment or voting powers and that if the pledgee were deemed to be the beneficial owner of the pledged securities immediately upon default, serious practical compliance problems would be presented. In recognition of these problems, the Commission adopted rule 13d-3(d)(3) stating, generally, that a pledgee, after default, would not be deemed the beneficial owner of the pledged securities, provided certain conditions were met.[3] The conditions relevant to the action taken in this release are the requirement that the pledge agreement not grant to the pledgee the power to dispose or to direct the disposition of the pledged securities prior to default, and the provision which limits the application of the pledge provision of the rule to those agreements in which the pledgee is an institutional investor, as specified in rule 13d-1(b)(1)(ii).

It has been pointed out that in view of customary margin account contracts, the condition that the pledge agreement not convey investment power prior to default might suggest that the broker-dealer would be the beneficial owner of all securities placed in such accounts, even prior to default. In view of practical necessities in the operation of margin accounts, the Commission recognizes that this condition concerning investment power should not be applied to such arrangements and has made an appropriate revision to rule 13d-3(d)(3). It should be recognized, however, that remaining conditions include requirements that the pledge be in the pledgee's ordinary course of business and not for the purpose nor with the effect of changing or influencing the control of the issuer, nor in connection with any transaction having such purpose or effect. It is also to be emphasized that the provisions concerning the beneficial ownership status of the pledgee generally offer no relief to the pledgor; inasmuch as the pledgor normally would have voting power or investment power over the pledged securities, the beneficial ownership of pledged securities, in a margin account or otherwise, would be attributable to the pledgor and aggregated with all other securities of such class beneficially owned by the pledgor, to determine such person's filing obligation under section 13(d).

The amendments contained here also include two other relatively minor revisions to rule 13d-3(d)(3). First, the provision containing the requirement that the pledgee be a person specified in rule 13d-1(b)(1)(ii) has been expanded to include persons meeting the conditions set forth in rule 13d-1(b)(1)(ii)(G), the provision discussed above concerning parent holding companies. Thus, the pledge provisions of rule 13d-3(d)(3) are applicable to parent holding companies and nonqualifying subsidiaries, but only in cases in which the aggregate amount of securities held by such persons does not exceed one percent.

Another amendment to rule 13d-3(d)(3) deletes from the introductory phrase of that rule the term "as to which there has been a default." That phrase might have been read as limiting the scope of the pledge provision and it is deleted to provide clarity as to the beneficial ownership status of pledged securities prior to default.

II. Certain Findings

As required by section 23(a)(2) of the Exchange Act, the Commission has specifically considered the impact which the amendments herein would have on competition. The Commission has found that these amendments will not significantly burden competition and, in any event, has determined that any possible resulting competitive burden will be far outweighed by, and is necessary and appropriate to achieve, the benefits of this information to investors.

III. Effective Date of the Amendments

The following amendments will be effective July 11, 1978.

IV. Authority

The Commission hereby amends rules 13d-1(b)(1)(ii)(G) and 13d-3(d)(3) pursuant to the authority set forth in sections 3(b), 13, 14, and 23 of the Exchange Act. The Commission finds that these amendments have already been generally subject to comment during the public fact-finding investigation in the matter of beneficial ownership, takeovers and acquisitions by foreign and domestic persons[4] or as a result of the proposals published in Exchange Act Release No. 34-13292 (42 FR 12355), or the issues raised in Exchange Act Release No. 34-13900 (42 FR 44964) and are either technical in nature or are less burdensome than previous requirements, such that further notice and rulemaking procedures pursuant to the Administrative Procedure Act (5 U.S.C. 553) are not necessary.

V. Text of Amended Rules

Part 240 of chapter II of title 17 of the Code of Federal Regulations is amended as follows:

1. § 240.13d-1(b)(1)(ii)(G) is revised to read as follows:

§ 240.13d-1 Filing of Schedules 13D and 13G.

* * * * *

(b) * * *
(1) * * *
(ii) * * *

(G) A parent holding company, provided the aggregate amount held directly by the parent, and directly and indirectly by its subsidiaries which are not persons specified in rule 13d-1(b)(ii) (A) through (F), does not exceed one percent of the securities of the subject class;

* * * * *

2. § 240.13d-3(d)(3) is revised to read as follows:

§ 240.13d-3 Determination of beneficial owner.

* * * * *

(d) * * *

(3) A person who in the ordinary course of business is a pledgee of securities under a written pledge agreement shall not be deemed to be the beneficial owner of such pledged securities until the pledgee has taken all formal steps necessary which are required to declare a default and determines that the power to vote or to direct the vote or to dispose or to direct the disposition of such pledged securities will be exercised, provided that:

(i) The pledgee agreement is bona fide and was not entered into with the purpose nor with the effect of chang-

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[3] As adopted in release No. 33-5925, rule 13d-3(d)(3) provides:

(3) A person who in the ordinary course of his business is a pledgee of securities under a written pledge agreement as to which there has been a default shall not be deemed to be the beneficial owner of such pledged securities until the pledgee has taken all formal steps necessary which are required to declare such default and determines that the power to vote or to direct the vote or to dispose or to direct the disposition of such pledged securities will be exercised: provided, that:

(i) The pledge agreement is bona fide, does not grant the power to vote or to direct the vote or to dispose or to direct the disposition of such pledged securities to the pledgee prior to default, and was not entered into with the purpose nor with the effect of changing or influencing the control of the issuer, nor in connection with any transaction having such purpose or effect, including any transaction subject to rule 13d-3(b); and

(ii) The pledgee is a person specified in rule 13d-1(b)(1)(ii).

[4] Exchange Act Release Nos. 11003 (September 9, 1974) (39 FR 33855) and 11088 (November 5, 1974) (39 FR 41223).

ing or influencing the control of the issuer, nor in connection with any transaction having such purpose or effect, including any transaction subject to rule 13d-3(b);

(ii) The pledgee is a person specified in rule 13d-1(b)(ii), including persons meeting the conditions set forth in paragraph (G) thereof; and

(iii) The pledgee agreement, prior to default, does not grant to the pledgee:

(A) The power to vote or to direct the vote of the pledged securities; or

(B) The power to dispose or direct the disposition of the pledged securities, other than the grant of such power(s) pursuant to a pledge agreement under which credit is extended subject to regulation T (12 CFR 220.1 to 220.8) and in which the pledgee is a broker or dealer registered under section 15 of the act.

* * * * *

(Secs. 3(b), 13(d)(1), 13(d)(2), 13(d)(5), 13(d)(6), 14(d)(1), 23; 48 Stat. 882, 894, 895, 901; sec. 203(a), 49 Stat. 704, sec. 8, 49 Stat. 1379; sec. 10, 78 Stat. 88a; secs. 2, 3, 82 Stat. 454, 455; secs. 1, 2, 3-5, 84 Stat. 1497; secs. 3, 18, 89 Stat. 97, 155; 15 U.S.C. 78c(b), 78m(d)(1), 89m(d)(2), 78m(d)(5), 78m(d)(6), 78n(d)(1), 78w.)

By the Commission.

SHIRLEY E. HOLLIS,
Assistant Secretary.

JUNE 30, 1978.

[FR Doc. 78-18995 Filed 7-10-78; 8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 77N-0119]

PART 131—MILK AND CREAM

Nonfat Dry Milk, Lowfat Dry Milk, Dry Whole Milk, and Dry Cream; Standards of Identity; Correction

AGENCY: Food and Drug Administration.

ACTION: Correction.

SUMMARY: This document corrects the final rule that was published in the FEDERAL REGISTER of Tuesday, May 9, 1978, by changing the CFR citation on page 19836.

DATE: Effective May 9, 1978.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: In FR Doc. 78-12513 appearing at page 19834 in the FEDERAL REGISTER of May 9, 1978, paragraph (d)(1) of § 131.127 *Nonfat dry milk fortified with vitamins A and D* (21 CFR 131.127) appearing on page 19836 is corrected in the third line by changing "16.131-16.18" to read "16.131-16.181."

Dated: July 5, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-19024 Filed 7-10-78; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

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

Prednisolone Sodium Phosphate Injection, Sterile

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Burns-Biotec Laboratories Division. The application provides for safe and effective use of prednisolone sodium phosphate intravenous injection in dogs and horses when an adrenal glucocorticoid and/or anti-inflammatory effect is required.

EFFECTIVE DATE: July 11, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, 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: Burns-Biotec Laboratories Division, Chromalloy Pharmaceutical, Inc., 7711 Oakport Street, Oakland, Calif. 94621, filed NADA 97-566V providing for intravenous injection of prednisolone phosphate in dogs and horses when an adrenal glucocorticoid and/or antiinflammatory effect is required. In addition, this document reflects the National Academy of Sciences/National Research Council (NAS/NRC) evaluation of a similar product.

The drug prednisolone sodium succinate was one of several adrenocortical steroids evaluated by the NAS/NRC Drug Efficacy Study Group. The evaluation results were published in the FEDERAL REGISTER of April 12, 1969 (34 FR 6447). The NAS/NRC concluded that the subject adrenocortical steroids are effective as anti-inflammatory agents. The Food and Drug Administration concurred with the conclusions of the Academy and stated:

> These drugs are synthetic corticosteroids and possess glucocorticoid activity. They are not species specific and differ only in their anti-inflammatory potency and ability to manifest mineralocorticoid properties.

The results of blood studies comparing intravenous injections of The Upjohn Co.'s prednisolone sodium succinate, which was evaluated by NAS/NRC, with Burns-Biotec's prednisolone sodium phosphate have demonstrated the bioequivalency of the two products.

This document amends the regulations to indicate those conditions of use for which applications for identical products need not include certain types of efficacy data required for approval in § 514.111(a)(5)(vi) of the animal drug regulations (21 CFR 514.111(a)(5)(vi)). In lieu of that data, approval may require bioequivalency or similar data as suggested in the guideline for submitting NADA's for NAS/NRC reviewed generic drugs, available from the office of the Hearing Clerk (HFA-305), Food and Drug Administration.

In accordance with the freedom of information regulations and § 514.11 (e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety data and information submittted to support approval of this NADA is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday.

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), part 522 is amended by revising § 522.1883, to read as follows:

§ 522.1883 Prednisolone sodium phosphate injection, sterile.

(a)(1) *Specifications.* Each milliliter contains 20 milligrams of prednisolone sodium phosphate (equivalent to 14.88 milligrams of prednisolone) in sterile aqueous solution.

(2) *Sponsor.* See No. 000864 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) It is used in treatment of dogs when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.[1]

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[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these

Footnotes continued on next page

(ii) It is administered intravenously in a dosage of 2½ to 5 milligrams of prednisolone sodium phosphate per pound of body weight, initially for shock and shock-like states, followed by equal maintenance doses at 1-, 3-, 6-, or 10-hour intervals as determined by the condition of the animal. If permanent use is required, oral therapy (tablets) may be substituted. If therapy is to be withdrawn after prolonged use, reduce daily dose gradually over a number of days.

(iii) Do not use in viral infections. Except in emergency therapy, do not use with tuberculosis, chronic nephritis, Cushing's disease, or peptic ulcers. With infections, use appropriate antibacterial therapy with, and for at least 3 days after, discontinuance of use and disappearance of all signs of infection.[1]

(iv) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

(b)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of prednisolone phosphate (as prednisolone sodium phosphate).

(2) *Sponsor.* See No. 000845 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer intravenously as follows:

(*a*) *Horses.* 50 to 100 milligrams in ½ to 1 minute.[1] May be repeated at 12-, 24-, or 48-hour intervals in inflammatory, allergic, and stress conditions as required.

(*b*) *Dogs.* 2.5 to 5 milligrams per pound of body weight followed by maintenance doses at 1-, 3-, 6-, or 10-hour intervals for shock or shock-like states. If permanent use is required, oral therapy (tablets) may be substituted. When therapy is withdrawn after prolonged use, reduce daily dose gradually over a number of days.

(ii) *Indications for use.* It is used when an adrenal glucocorticoid and/or anti-inflammatory effect is required.[1]

(iii) *Limitations.* (*a*) Do not use in viral infections. Except in emergency therapy, do not use in animals with tuberculosis, chronic nephritis, or Cushing's disease. With infections, use appropriate antibacterial therapy with, and for at least 3 days after, discontinuance of use and disappearance of all signs of infection.

(*b*) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(*c*) Do not use in horses intended for food.

(*d*) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

Effective date. This regulation is effective July 11, 1978.

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

Dated: June 27, 1978.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary Medicine

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[4110-03]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Nystatin-Neomycin-Thiostrepton-Triamcinolone Acetonide Ointment

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application (NADA) filed by E. R. Squibb & Sons, Inc., providing for the safe and effective use of a topical vanishing cream ointment for the treatment of superficial bacterial and candidal infections in dogs and cats. This product is equivalent to a topical petrolatum base ointment that is an approved new animal drug.

EFFECTIVE DATE: July 11, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 560 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: E. R. Squibb & Sons, Inc., P.O. Box 4000, Princeton, N.J. 08540, filed an NADA (96-676V) providing for the safe and effective use of a nystatin, neomycin, thiostrepton, and triamcinolone acetonide vanishing cream ointment for topical treatment of dogs and cats. This product is used as an anti-inflammatory, antipruritic, antifungal, and antibacterial agent for superficial bacterial infections, and for inflammation and dry or exudative dermatitis associated with bacterial or candidal infections. This drug is similar to the petrolatum base ointment approved in § 524.1600a (21 CFR 524.1600a). The petrolatum ointment, originally approved June 9, 1960, was reviewed by the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Implementation (DESI) Panel and found to be effective with certain labeling modifications. A supplement reflecting this approval's compliance with the NAS/NRC review was published in the FEDERAL REGISTER of April 22, 1971 (36 FR 7583). The dermatologic claims of the vanishing cream ointment were found to be bioequivalent to the petrolatum base formulation. Both drugs have the same sponsor.

These amendments set forth those uses for which identical products can be approved without including certain types of efficacy data as required by § 514.111(a)(5)(iv) of the animal drug regulations. In lieu of that data, approval may require bioequivalency or similar data as noted in the guideline for submitting NADA's for NAS/NRC reviewed generic drugs, available from the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. In addition, the existing regulations for use of these drugs are editorially revised to reflect the current format.

In accordance with the freedom of information regulations and § 514.11 (e)(2)(ii) (21 CFR 514.11(e)(2)(ii) of the animal drug regulations, a summary of the safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk, (HFA-305), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday.

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, part 524 is amended in § 524.1600a by revising paragraphs (a) and (c) to read as follows:

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment.

(a) *Specifications.* Each milliliter of petrolatum base or each gram of vanishing cream base ointment contains: 100,000 units of nystatin; neomycin sulfate equivalent to 2.5 milligrams of neomycin base; 2,500 units of thiostrepton; and 1.0 milligram of triamcinolone acetonide.

* * * * *

(c) *Conditions of use.*—(1) *Amount.* (i) For topical dermatological use:

Footnotes continued from last page
uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.