

**ACTION:** Publication of Staff and Accounting Bulletin.

**SUMMARY:** These interpretations of the staff of the Commission provide guidance to registrants in disclosing replacement cost data. Large nonfinancial registrants are required to disclose in their financial statements certain replacement cost information relating to inventories and productive capacity. In the staff's view, (1) registrants have flexibility in changing the methods and assumptions used in estimating the required replacement cost information from those used in the prior year, and (2) disclosures of replacement cost information, including those in material pertaining to proposed business combinations, should avoid simplistic presentations of the information.

**DATE:** January 31, 1978.

**FOR FURTHER INFORMATION CONTACT:**

Gary A. Zell, 202-376-8019 or Richard C. Adkerson 202-755-1671, Office of the Chief Accountant, Securities and Exchange Commission, Washington, D.C. 20549.

**SUPPLEMENTARY INFORMATION:** The statements in Staff Accounting Bulletins are not rules or interpretations of the Commission nor are they published as bearing the Commission's official approval; they represent interpretations and practices followed by the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the Federal securities laws.

GEORGE A. FITZSIMMONS,  
*Secretary.*

JANUARY 31, 1978.

STAFF ACCOUNTING BULLETIN No. 20

The following interpretations provide guidance to registrants in disclosing the replacement cost information required by 17 CFR 210.3-17 as adopted in Accounting Series Release No. 190 (41 FR 13596).

TOPIC 6: INTERPRETATIONS OF ACCOUNTING SERIES RELEASES

I. Accounting Series Release No. 190—Amendments to regulation S-X requiring disclosure of certain replacement cost data (§ 210.3-17).

2. GENERAL

g. *Disclosure of comparative replacement cost data.*—Section 210.3-17 requires that registrants disclose certain replacement cost information in financial statements for the current year and, beginning for years

ending on or after December 25, 1977, for the immediately preceding year. Certain registrants may wish, in developing estimates of the required data for the current year, to change either the methods used to estimate the data in the preceding year or to change the assumptions underlying such estimates.

Question 1

Is it appropriate to change the methods or the assumptions, or both, used to develop the estimates of replacement cost information from those used previously?

Interpretive response

Yes. The Commission in Accounting Series Release No. 190 encouraged meaningful experimentation in developing estimates of replacement cost information. If registrants conclude that methods or assumptions different from those used previously provide more appropriate or, while still resulting in acceptable estimates, less costly estimates of the required replacement cost information, they should not feel constrained to the methods or assumptions used in prior years.

Question 2

What disclosures does the staff suggest when such changes are made in the replacement cost methods or assumptions?

Interpretive response

Registrants should describe changes in the methods and assumptions used to estimate replacement cost information in the manner they consider appropriate. At a minimum, a registrant making changes of this nature should comment briefly on the changes and the reasons for making them. Registrants are not required either to restate the replacement cost information presented for the prior year to reflect newly adopted methods and assumptions or to provide any reconciliation of the amounts disclosed in the prior year using the new and old bases for estimating the data. The prior year data may be restated to reflect the new methods or assumptions if the registrant believes that restatement is appropriate. Restatement of the replacement cost information presented in the prior year would be necessary to reflect (a) corrections of errors, such as omissions and mathematical mistakes and (b) restatements of financial statements required by generally accepted accounting principles, such as for a business combination accounted for as a pooling-of-interests.

9. MISCELLANEOUS

c. *Presentation of replacement cost information in material pertaining to proposed business combinations.*

Facts

Certain registrants have recently disclosed replacement cost information in material filed with the Commission relating to proposed business combinations. For instance, one such registrant disclosed the difference between the historical cost and replacement cost of inventories and productive capacity as additional indicated stockholders' equity per share with no adjustments for income taxes or other possible effects.

Question

Does the staff consider such use of replacement cost data appropriate?

Interpretive response

The staff would consider the specific situation discussed above to be an inappropriate use of the replacement cost information required by § 210.3-17. Converting the data to additional stockholders' equity on a basis of accounting other than generally accepted accounting principles is a complex undertaking which requires consideration of matters other than the replacement cost of inventories and productive capacity. Adding the difference between the replacement costs and historical costs of these assets directly to reported stockholders' equity is a simplistic use of the data about which the Commission cautioned investors and analysts in Accounting Series Release No. 190.

[FR Doc. 78-3374 Filed 2-6-78; 8:45 am]

[4110-07]

Title 20—Employees' Benefits

CHAPTER III—SOCIAL SECURITY ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Reg. No. 4]

PART 404—FEDERAL OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE

Subpart J—Procedures, Payment of Benefits, and Representation of Parties

Consolidation of Hearings in Disability Cases With Common Issues

AGENCY: Social Security Administration, HEW.

ACTION: Final rule.

**SUMMARY:** These amendments provide for consolidation of hearings on the issue of medical improvement in cases of dual entitlement under both the Social Security Disability (Title II) and the Supplemental Security Income (Title XVI) programs when the individual has a right to a hearing under the title XVI program. They are needed to eliminate the mandatory reconsideration step for title II appeals. Through bypassing the reconsideration step under the title II program the common issues will be resolved in a single hearing and at an earlier point in time.

**EFFECTIVE DATE:** These amendments shall be effective on February 7, 1978.

**FOR FURTHER INFORMATION CONTACT:**

Ms. Dorothy E. Algea, Legal Assistant, Office of Policy and Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, Md. 21235, telephone 301-594-5587.

**SUPPLEMENTARY INFORMATION:** Regulations No. 4 (i.e., 20 CFR 404.917) now require reconsideration

review as the first appellate step after the initial determination in all title II disability insurance claims. Regulations No. 16, on the other hand, provide for a hearing as the first appellate step after the initial cessation decision due to medical improvement in supplemental security income disability cases (see 20 CFR 416.1426).

Since an individual receiving payments based on disability or blindness under both the Federal Old-Age, Survivors, and Disability Insurance program and the Supplemental Security Income program is in needy financial circumstances, it is important to provide him or her with the protection of procedural due process and to decide the issue of medical cessation of blindness or disability promptly. Since presiding officers at hearings (like all other employees) are governed by the regulations (20 CFR 404.909, 404.910, and 404.917(a)) which apply to all types of title II retirement, survivors, and disability claims, it is necessary to align those regulations with the title XVI regulations (20 CFR 416.1425(a)(4) and 416.1436(b)) so there is no opportunity for dismissal of requests for hearings under title II in cases where the common issue of medical cessation of blindness or disability is properly before them under title XVI. By amending §§ 404.910 and 404.917 to show that the first appellate step in an appropriate dual entitlement case is the hearing stage, dismissals of title II hearing requests will be prevented and smooth and prompt processing of consolidated hearings assured. Bypassing the administratively mandated reconsideration step will not adversely affect the rights of any claimant. Elimination of the reconsideration step in concurrent title II-title XVI medical cessation cases in no way affects the payment of benefits.

On August 1, 1977, there was published in the FEDERAL REGISTER (42 FR 38918-38919) a notice of proposed rule-making setting forth proposed amendments to the regulations providing for consolidation of hearings on the issue of medical improvement in cases of dual entitlement under both the Social Security Disability (Title II) and the Supplemental Security Income (Title XVI) programs which involve the common issue of cessation of blindness or disability. Interested parties were given the opportunity to submit, not later than September 15, 1977, data, views, and arguments pertaining to the proposal.

The only comment received was from the State of Mississippi. It commended the Social Security Administration for this positive step toward bringing uniformity to program requirements. In the absence of any unfavorable comment, the proposed regulations are hereby adopted without change and are set forth below.

(Secs. 205, 221(d), 1102, Social Security Act, as amended; 49 Stat. 624, as amended by 53 Stat. 1368, 87 Stat. 632, 88 Stat. 1082, 49 Stat. 647, as amended by 86 Stat. 1489 (42 U.S.C. 405, 421(d), 1302))

(Catalog of Federal Domestic Assistance Program No. 13.802, Social Security—Disability Insurance.)

NOTE.—The Social Security Administration has determined that this document does not require preparation of an Economic Impact Statement under Executive Order 11821 (November 27, 1974), as amended by Executive Order 11949 (December 31, 1976), and OMB Circular A-107.

Dated: November 25, 1977.

J. B. CARDWELL,  
Commissioner of Social Security.

Approved: February 1, 1978.

JOSEPH A. CALIFANO, JR.,  
Secretary of Health,  
Education, and Welfare.

Part 404 of Chapter III of Title 20 of the Code of Federal Regulations is amended as set forth below:

1. Section 404.910 is revised to read as follows:

§ 404.910 Reconsideration; right to reconsideration.

The Social Security Administration shall, except as provided in § 404.910(d), reconsider an initial determination if a written request for reconsideration is filed, as provided in § 404.911:

(a) By or for the party to the initial determination (see § 404.905).

(b) By an individual as a wife, widow, divorced wife, surviving divorced wife, surviving divorced mother, husband, widower, child, parent, individual alleging equitable entitlement to a lump sum, or representative of a decedent's estate, who makes a showing in writing that his or her rights with respect to monthly benefits, a lump sum, a period of disability, or entitlement to hospital or supplementary medical insurance benefits, may be prejudiced by such determination. Such request for reconsideration is not applicable under this paragraph with respect to the revision of the Social Security Administration's earnings records.

(c) By a person as a widow, divorced wife, surviving divorced wife, surviving divorced mother, widower, child, parent, or individual alleging equitable entitlement to a lump sum, or representative of the decedent's estate relating to the revision of the Social Security Administration's record of the earnings (see § 404.905(g)) of a deceased individual.

(d) When the Social Security Administration has made an initial determination under title II that blindness or disability has ceased due to medical improvement and a hearing or right to hearing is pending under title XVI with respect to the same party and the same issue, appeal of the initial deter-

mination under title II shall be made directly to the hearing as provided in § 404.917.

2. Section 404.917(a) is amended to read as follows:

§ 404.917 Hearing; right to hearing.

An individual has a right to hearing about any matter designated in § 404.905, if:

(a) The Social Security Administration has made:

(1) An initial determination and a reconsideration of the initial determination; or

(2) A revised determination of an initial or reconsideration determination as provided in § 404.961; or

(3) An initial determination that blindness or disability has ceased due to medical improvement: *Provided*, That there is also pending a hearing or right to hearing under title XVI with respect to the same party and the same issue; and

[FR Doc. 78-3231 Filed 2-6-78; 8:45 am]

[4110-03]

Title 21—Food and Drugs

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

SUBCHAPTER A—GENERAL

[Docket No. 76C-0425]

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

D. & C. Red No. 34; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of December 27, 1976, of a regulation concerning the use of D. & C. Red No. 34 in externally applied drugs and cosmetics.

DATES: Effective date confirmed: December 27, 1976.

FOR FURTHER INFORMATION CONTACT:

Gerard L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: A regulation published in the FEDERAL

REGISTER of November 23, 1976 (41 FR 51592), that added §§ 74.1334 and 74.2334 (21 CFR 74.1334 and 74.2334) (formerly §§ 8.4128 and 8.7195 prior to recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)), to provide for safe use of D. & C. Red No. 34 in externally applied drugs and cosmetics and amended § 81.1 (21 CFR 81.1, formerly 21 CFR 8.501) by deleting D. & C. Red No. 34 from the provisionally listed colors in paragraph (b). The regulation of November 23, 1976 also amended the identity nomenclature and specifications for the certification of D. & C. Red No. 34 § 82.1334 (21 CFR 82.1334, formerly 21 CFR § 9.179) to reference § 74.1334.

Under the Federal Food, Drug, and Cosmetic Act (secs. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), notice is given that no objections or requests for hearing were filed in response to the regulation of November 23, 1976. The Commissioner has determined, in the absence of such objections, that the notice that appeared in the FEDERAL REGISTER of March 4, 1977 (42 FR 12424) that stayed the regulation was inappropriate. Therefore, the Commissioner is nullifying the stay of effectiveness and, accordingly, the amendments listing D. & C. Red No. 34 promulgated by the order of November 23, 1976 became effective on December 27, 1976.

Dated: February 1, 1978.

WILLIAM F. RANDOLPH,  
Acting Associate Commission  
for Compliance.

[FR Doc. 78-3199 Filed 2-6-78; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

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

Uredofos Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application filed by Affiliated Laboratories Division, Whitmoyer Laboratories, providing for use of uredofos tablets for removal of certain intestinal worms in dogs and cats.

EFFECTIVE DATE: February 7, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veteri-

nary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., 1 Gibraltar Plaza, Horsham, Pa. 19044, filed a new animal drug application (NADA) (100-745V) providing for oral administration of the organophosphate uredofos for removal of roundworms, hookworms, and tapeworms in dogs and cats and whipworms in dogs.

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 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 (HFC-20), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

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 520 is amended by adding new § 520.2645 to read as follows:

§ 520.2645 Uredofos tablets.

(a) *Chemical name.* Diethyl [[[(4-methylphenyl)-sulfonyl]amino]carbonyl]amino]phenyl]aminothioxomethyl] phosphoramidate.

(b) *Specifications.* Each tablet contains 25, 62.5, 125, 250, or 500 milligrams of uredofos.

(c) *Sponsor.* See No. 011794 in § 510.600(c) of this chapter.

(d) *Conditions of use—(1). Amount.* 25 milligrams per pound (55 milligrams per kilogram) body weight.

(2) *Indications for use—(i). Dogs.* For removal of roundworms (*Toxocara canis*, *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Dipylidium caninum*, *Taenia pisiformis*).

(ii) *Cats.* For removal of roundworms (*Toxocara cati*), hookworms (*Ancylostoma tubaeforme*, *A. Braziliensis*), and tapeworms (*Taenia taeniaformis*).

(3) *Limitations.* (i) For roundworms, hookworms, and tapeworms in dogs and cats, administer single oral dose of 25 milligrams per pound (55 milligrams per kilogram) body weight. For maximum efficacy in removing whipworms from dogs, administer same single oral dose and repeat treatment in approximately 24 hours.

(ii) The drug is a cholinesterase inhibitor. It is recommended that dogs being treated for whipworm infesta-

tion be kept under observation for 12 hours following the second dose. Do not use simultaneously or within a few days of exposure to or treatment with cholinesterase-inhibiting drugs.

(iii) Do not use with other anthelmintics.

(iv) Do not administer to animals showing signs of mechanical blockage of intestinal tract or infectious disease.

(v) Do not administer to cats or puppies under 10 days of age or under 1 pound of body weight.

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

*Effective date.* This regulation becomes effective February 7, 1978.

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

Dated: February 1, 1978.

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

[FR Doc. 78-3203 Filed 2-6-78; 8:45 am]

[4110-03]

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

Sterile Triamcinolone Acetonide Suspension;  
NAS/NRC Update

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect previously unpublished approval of a new animal drug application (NADA) filed by E. R. Squibb & Sons, Inc., providing for use of a synthetic corticosteroid for treatment of dogs, cats, and horses.

EFFECTIVE DATE: February 7, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert A. Baldwin, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: E. R. Squibb & Sons, Inc., P.O. Box 4000, Princeton, N.J. 08540, filed an NADA (12-198V) providing for use of a synthetic corticosteroid for treatment of inflammatory disorders in dogs, cats, and horses; plus treatment of arthritis and allergic and dermatologic disorders in dogs and cats. In addition, a supplemental NADA revises the indications for use. These were approved without publications in the FEDERAL REGISTER reflecting the approval.

Triamcinolone acetonide was one of several adrenocortical steroids that were subject of the National Academy

of Science/National Research Council (NAS/NRC), drug efficacy study implementation report published in the FEDERAL REGISTER of April 12, 1969 (34 FR 8447). The NAS/NRC report concluded that several adrenocortical steroids are effective as anti-inflammatory agents. The agency concurred with the Academy's conclusions. In the cited publication, the agency stated:

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

Although Squibb's dosage-form tablet for oral administration differs from that of the NAS/NRC report, the product's bioavailability data have demonstrated its bioequivalency. A supplemental NADA, filed by Squibb in response to the NAS/NRC review, revised the indications for use. No new efficacy data were required.

This document amends the regulations to indicate by footnote those conditions of use for which applications for identical products need not include certain types of efficacy data as required for approval in § 514.111(a)(5)(vi) (21 CFR 514.111(a)(5)(vi)) of the animal drug regulations. In lieu of that data, approval may require bio-equivalency or similar data as suggested in the guideline for submitting NADA's for NAS/NRC reviewed generic drugs, available with the Hearing Clerk (HFC-20), Food and Drug Administration.

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 safety and effectiveness data and information submitted to support approval of this NADA is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFC-20), Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

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 adding new § 522.2483, to read as follows:

§ 522.2483 Sterile triamcinolone acetonide suspension.

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams triamcinolone acetonide.

(b) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1). Amount—(i) Dogs and cats.*

(a) *Intramuscular or subcutaneous.* Single injection of 0.05 to 0.1 milligram (mg.) per pound of body weight

in inflammatory, arthritic, or allergic disorders. Single injection of 0.1 mg. per pound of body weight in dermatologic disorders. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.<sup>1</sup>

(b) *Intralesional.* 1.2 to 1.8 mg., divided in several injections, spaced around the lesion at 0.5 to 2.5 centimeters apart depending on the size. At any one site the dose injected should not exceed 0.8 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.

(c) *Intra-articular and intrasynovial.* Single injection of 1 to 3 mg. dose, dependent on size of joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 3 mg.

(ii) *Horses—(a) Intramuscular or subcutaneous.* Single injection of 0.01 to 0.02 mg. per pound of body weight. Usual dose, 12 to 20 mg.

(b) *Intra-articular and intrasynovial.* Single injection of 6 to 18 mg. dose, dependent on size of joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 18 mg.

(2) *Indications for use.* Treatment of inflammation and related disorders in dogs, cats, and horses<sup>2</sup>; and management and treatment of acute arthritis and allergic and dermatologic disorders in dogs and cats.

(3) *Limitations.* (i) Do not use in viral infections. With bacterial infections, appropriate antibacterial therapy should be used.

(ii) Do not use in animals with tuberculosis, chronic nephritis, or cushingoid syndrome, except for emergency therapy.

(iii) Not for use in horses intended for food.

(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) Do not use in the treatment of laminitis.

(vi) Intra-articular injection in equine leg injuries may produce osseous metaplasia.

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

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

Effective Date: February 7, 1978.

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

Dated: February 1, 1978.

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

[FR Doc. 78-3201 Filed 2-6-78; 8:45 am]

#### [1505-01]

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

##### Gentamicin Sulfate Injection

##### Correction

In FR Doc. 78-914 appearing on page 1941 in the issue of Friday, January 13, 1978, the 1st line should read, "AGENCY: Food and Drug Administration."

#### [4110-03]

#### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

##### Monensin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Products Co., providing for a 60-grams-per-pound monensin premix for chickens.

EFFECTIVE DATE: February 7, 1978.

FOR FURTHER INFORMATION CONTACT:

Adriano R. Gabuten, Bureau of Veterinary Medicine (HFV-149), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: Elanco Products Co., A Division of Eli Lilly & Co., 740 S. Alabama Street, Indianapolis, Ind. 46206, filed a supplemental NADA (38-878V) providing for a 60-grams-per-pound monensin premix intended for subsequent manufacture of a complete feed for broiler and replacement chickens. The feed thus produced would aid in prevention of coccidiosis. The complete feed produced from this higher concentration premix is to be used in accordance with currently approved conditions of use. This independent action has not required a reevaluation of the parent NADA and does not constitute a reaffirmation of the drug's safety and effectiveness.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82