for the color additives aluminum powder, annatto, bronze powder, carmine, carotene, chromium hydroxide green, chromium oxide greens, copper metallic powder, ferric ferrocyanide (iron blue), guanine (pearl essence), mica, and zinc oxide listed in paragraph (g) are changed to read "August 30, 1977."

Effective date: July 1, 1977.

(Sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note).)

Dated: June 28, 1977.

JOSEPH J. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-18942 Filed 6-30-77;8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Docket No. 75N-0372]

PART 500—GENERAL

Subpart B—Specific Administrative Rulings and Decisions

HEXACHLOROPHENE

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document requires approved new animal drug applications (NADA's) for animal drugs containing hexachlorophene for use in or on animals, with certain exceptions. The regulation results from concern over the known toxicity of hexachlorophene to humans.

EFFECTIVE DATE: August 1, 1977.

FOR FURTHER INFORMATION CONTACT:

Howard Meyers, Bureau of Veterinary Medicine (HFV-214), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, (301-443-3183).

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs proposed, in the FEDERAL REGISTER of June 23, 1976 (41 FR 25911), new § 500.46 Hexachlorophene in animal drugs to require approved NADA's for animal drugs containing hexachlorophene for use in or on animals, other than as part of a product preservative system at a level of not more than 0.1 percent in topical preparations for use in non-food-producing animals.

The proposed regulation resulted from the Commissioner's concern over the known toxicity of hexachlorophene to humans and the lack of adequate data to support its safe and effective use in or on animals other than as part of a product preservative system at a level of not more than 0.1 percent in topical preparations for use in non-food-producing animals.

Interested persons were given until August 23, 1976, to file written comments on the proposal. One response was received to the proposal, that from a practicing veterinarian who requested moderation of the "extreme stand."

The Commissioner concludes that the regulation as proposed is apropriate. It is the statutory responsibility of the Food and Drug Administration to require that drugs be safe and effective. Because animal drugs containing hexachlorophene above a preservative level of 0.1 percent in non-food-producing animals have not been demonstrated to be safe and effective by current standards such products are new animal drugs requiring approved NADA's for their continued use.

The respondent also made several other comments, which, along with the Commissioner's response, are as follows:

1. Hexachlorophene is clinically effective when used topically for treating a generalized hemolytic staphylococcal infection of the skin of dogs.

The Federal Food, Drug, and Cosmetic Act requires that effectiveness be established by substantial evidence consisting of adequate and well-controlled investigations by experts on which it could reasonably be concluded that the drug has its purported effect (21 U.S.C. 360b(d)(3)). Therefore, opinions, even those of an expert, unless based upon such adequate and well-controlled investigations, do not qualify as substantial evidence establishing effectiveness.

2. Adequate directions for use can be given to protect humans from the potential hazards from use of the drug on animals.

The Commissioner concludes that, until hexachlorophene is shown to be safe and effective for its labeled uses, whether or not adequate directions for use can be given to protect humans from the potential hazards from the use of the drug on animals is irrelevant.

3. The potential hazard to humans is less from contamination with hexachlorophene than with hemolytic staphylococci, which are distributed throughout the house by infected animals.

The Commissioner concludes that the distribution of potentially harmful hemolytic staphylococci throughout the home can be avoided safely by other means.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 500 is amended by adding new § 500.46 to read as follows:

§ 500.46 Hexachlorophene in animal drugs.

(a) The Commissioner of Food and Drugs has determined that there are no adequate data to establish that animal drugs containing hexachlorophene are safe and effective for any animal use other than in topical products for use on non-food-producing animals as part of a product preservative system at a level not to exceed 0.1 percent; that there is no information on the potential risk to humans from exposure to hexachlorophene by persons who apply animal products containing the drug at levels higher than 0.1 percent; and that there is likewise no information on human exposure to animals on which these animal drugs have been used and no information on possible residues of hexachlorophene in edible products of food-producing animals treated with new animal drugs that contain any quantity of hexachlorophene.

(b) Animal drugs containing hexachlorophene for other than preservative use on non-food-producing animals at levels not exceeding 0.1 percent are considered new animal drugs and shall be the subject of new animal drug applications (NADA's).

(c) Any person currently marketing animal drugs that contain hexachlorophene other than as part of a product preservative system for products used on non-food-producing animals at a level not exceeding 0.1 percent shall submit a new animal drug application, supplement an existing application, or reformulate the product by September 29, 1977. Each application or supplemental application shall include adequate data to establish that the animal drug is safe and effective. If the animal drug is currently subject to an approved new animal drug application, each reformulation shall require an approved supplemental application. The interim marketing of these animal drugs may continue until the application has been approved, until it has been determined that the application is not approvable under the provisions of § 514.111 of this chapter, or until an existing approved application has been withdrawn.

(d) After September 29, 1977, animal drugs that contain hexachlorophene other than for preservative use on non-food-producing animals at a level not exceeding 0.1 percent that are introduced into interstate commerce shall be deemed to be adulterated within the meaning of section 501(a)(5) of the act (21 U.S.C. 351(a)(5)) unless such animal drug application submitted pursuant to paragraph (c) of this section. Action to withdraw approval of new animal drug applications will be initiated if supplemental new animal drug applications have not been submitted in accordance with this section.

(e) New animal drug applications submitted for animal drugs containing hexachlorophene for use in or on food-producing animals shall include adequate data to assure that edible products from treated animals are safe for human consumption under the labeled conditions of use.

Effective date: This regulation becomes effective August 1, 1977.

(Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)).)

Dated: June 27, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-18939 Filed 6-30-77;8:45 am]

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

Dichlorophene and Toluene Capsules

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 The Farnam Companies, Inc., providing for safe and effective use of dichlorophene/toluene capsules for treating certain helminth infections in dogs and cats.

EFFECTIVE DATE: July 1, 1977.

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: Under section 512(i) of the Federal Food, Drug, and Cosmetic Act, § 520.580 of the animal drug regulations is amended to reflect approval of a new animal drug application (NADA 107-189V) filed by The Farnam Companies, Inc., 8701 North 29th St., Omaha, NE 68112.

In accordance with § 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 the approval of this application 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, between the hours of 9 a.m. and 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), § 520.580 is amended by revising paragraph (c)(1) to read as follows:

§ 520.580 Dichlorophene and toluene capsules.

* * * * *

(c)(1) *Sponsor.* Nos. 000010, 000081, 000124, 000856, 010290, 011519, 011536, 011614, 015563, 017135, and 023851 in § 510.600(c) of this chapter.

* * * * *

Effective date: This amendment shall be effective July 1, 1977.

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

Dated: June 24, 1977.

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

[FR Doc.77-18038 Filed 6-30-77;8:45 am]

Title 26—Internal Revenue

CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY

PERSONS WITH WHOM HAND CARRIED RETURNS MAY BE FILED

[T.D. 7495]

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains amendments to the regulations relating to the place for filing returns and other documents which are filed by hand carrying. These regulations provide necessary guidance for compliance with the law relating to filing requirements for returns and other documents and affect taxpayers generally.

DATE: These regulations are effective on July 1, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. Larry Smith of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224 (Attention: CC:LR:T) (202-566-3909).

SUPPLEMENTARY INFORMATION:

BACKGROUND

This document contains amendments to regulations promulgated under the authority of section 6091 which relate to the place for filing returns and other documents which are filed by hand carrying. Present regulations generally permit returns and other documents which are filed by hand carrying to be filed only with district directors of internal revenue. The amendments contained in this document permit returns and other documents which are filed by hand carrying to be filed with the heads of area, zone or local offices constituting permanent posts of duty within internal revenue districts as well as with district directors.

DRAFTING INFORMATION

The principal author of this regulation was Mr. Larry Smith of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

ADOPTION OF AMENDMENTS TO THE REGULATIONS

Accordingly, 26 CFR Parts 1, 20, 25, 31, 46, 48, 49, 53 and 301 are amended as follows:

SUBCHAPTER A—INCOME TAX

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

PARAGRAPH 1. The last sentence of § 1.6031-1(e)(1)(ii) is revised to read as follows:

§ 1.6031-1 Return of partnership income.

* * * * *

(e) *Place and time for filing returns*—(1) *Place for filing* * * *

(ii) *Returns filed with service centers* * * * Returns which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) in accordance with paragraph (e)(1)(i) of this section.

* * * * *

PAR. 2. Paragraph (d)(1) and (2) of § 1.6091-2 is revised to read as follows:

§ 1.6091-2 Place for filing income tax returns.

* * * * *

(d) *Hand-carried returns.* * * *

(1) *Persons other than corporations.* Returns of persons other than corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (a) of this section.

(2) *Corporations.* Returns of corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (b) of this section.

* * * * *

SUBCHAPTER B—ESTATE AND GIFT TAXES

PART 20—ESTATE TAXES

PAR. 3. Paragraph (a)(2) of § 20.6091-1 is revised to read as follows:

§ 20.6091-1 Place for filing returns or other documents.

(a) *General rule.* * * *

(2) The district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) in whose district the decedent was domiciled at the time of his death, if paragraph (1) does not apply.

* * * * *

PART 25—GIFT TAXES

PAR. 4. The last sentence of § 25.6091-1(b) is revised to read as follows:

§ 25.6091-1 Place for filing returns and other documents.

* * * * *

(b) *Returns filed with service centers.* * * * Returns which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) in accordance with paragraph (a) of this section.

* * * * *

SUBCHAPTER C—EMPLOYMENT TAXES

PART 31—EMPLOYMENT TAXES; APPLICABLE ON AND AFTER JANUARY 1, 1955

PAR. 5. Paragraph (e) (1) and (2) of § 31.6091–1 is revised to read as follows:

§ 31.6091–1 Place for filing returns.

* * * * *

(e) *Hand-carried returns.* * * *

(1) *Persons other than corporations.* Returns of persons other than corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (a) of this section.

(2) *Corporations.* Returns of corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (b) of this section.

* * * * *

SUBCHAPTER D—MISCELLANEOUS EXCISE TAXES

PART 46—MISCELLANEOUS EXCISE TAXES PAYABLE BY RETURN

PAR. 6. Paragraph (e) (1) and (2) of § 46.6091–1 is revised to read as follows:

§ 46.6091–1 Place for filing returns.

* * * * *

(e) *Hand-carried returns.* * * *

(1) *Persons other than corporations.* Returns of persons other than corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (a) of this section.

(2) *Corporations.* Returns of corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (b) of this section.

* * * * *

PART 48—MANUFACTURERS AND RETAILERS EXCISE TAXES

PAR. 7. Paragraph (e) (1) and (2) of § 48.6091–1 is revised to read as follows:

§ 48.6091–1 Place for filing returns.

* * * * *

(e) *Hand-carried returns.* * * *

(1) *Persons other than corporations.* Returns of persons other than corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (a) of this section.

(2) *Corporations.* Returns of corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (b) of this section.

* * * * *

PART 49—FACILITIES AND SERVICES EXCISE TAXES

PAR. 8. Paragraph (e) (1) and (2) of § 49.6091–1 is revised to read as follows:

§ 49.6091–1 Place for filing returns.

* * * * *

(e) *Hand-carried returns.* * * *

(1) *Persons other than corporations.* Returns of persons other than corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (a) of this section.

(2) *Corporations.* Returns of corporations which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) as provided in paragraph (b) of this section.

* * * * *

PART 53—FOUNDATION EXCISE TAXES

PAR. 9. The last sentence of § 53.6091–1 (c) is revised to read as follows:

§ 53.6091–1 Place for filing chapter 42 tax returns.

* * * * *

(c) *Returns filed with service centers.* * * * Returns which are filed by hand carrying shall be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) in accordance with paragraph (a) or (b) of this section, whichever is applicable.

* * * * *

SUBCHAPTER F—PROCEDURE AND ADMINISTRATION

PART 301—PROCEDURE AND ADMINISTRATION

PAR. 10. The first sentences of paragraph (b) (1) and (2) of § 301.6091–1 are revised to read as follows:

§ 301.6091–1 Place for filing returns and other documents.

* * * * *

(b) *Exception for hand-carried documents other than returns.* * * *

(1) *Persons other than corporations.* If a document, other than a return, of a person (other than a corporation) is hand carried, and if the document is otherwise required to be filed with a service center, such document may be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) for the internal revenue district in which is located the legal residence or principal place of business of such person, or, in the case of an estate, the internal revenue district in which was the domicile of the decedent at the time of his death. * * *

(2) *Corporations.* If a document, other than a return, of a corporation is hand carried, and if the document is otherwise required to be filed with a service center, such document may be filed with the district director (or with any person assigned the administrative supervision of an area, zone or local office constituting a permanent post of duty within the internal revenue district of such director) for the internal revenue district in which is located the principal place of business or principal office or agency of the corporation.

* * * * *

Because the amendments made by this Treasury decision are permissive, it is unnecessary to issue it with notice and public procedure thereon under subsection (b) of section 553 of title 5 of the United States Code.

(Sec. 6091, 7805, Internal Revenue Code of 1954, (68A Stat. 917; 26 U.S.C. 7805))

WILLIAM E. WILLIAMS,
Acting Commissioner of Internal Revenue.

Approved: June 24, 1977.

LAURENCE N. WOODWORTH,
Assistant Secretary of the Treasury.

[FR Doc.77-18855 Filed 6-29-77;9:00 am]

[T.D. 7493]

PART 31—EMPLOYMENT TAXES; APPLICABLE ON AND AFTER JANUARY 1, 1955

Group-Term Life Insurance, Wage Continuation Payments, and Moving Expenses

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final regulations relating to withholding with respect to group-term life insurance, wage continuation payments, and moving expenses. Changes in the applicable tax law were made by the Revenue Act of 1964. These regulations provide necessary guidance for compliance with the law, and affect all persons who may be required to withhold with respect to group-term life insurance, wage continuation payments, and moving expenses.

DATE: The regulations apply retroactively and are effective in accordance