(i) *Vaccines and Related Biological Products Advisory Committee.* (*a*) Date established: December 31, 1979.

(*b*) Function: Reviews and evaluates available data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

* * * * *

Effective date. Since this is a technical conforming amendment to Part 14, the Commissioner finds that there is good cause for the rule to be effective immediately upon publication in the Federal Register, (February 15, 1980).

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: February 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-4896 Filed 2-14-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 16

Hearings for Granting (or Denying) Exemptions or Variances

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is amending the procedural regulations to add to the list of statutory provisions for regulatory hearings the provision for granting or denying exemptions or variances from device good manufacturing practice requirements. Because this is merely a technical change, notice, public comment, and delayed effective date are unnecessary.

EFFECTIVE DATE: February 15, 1980.

FOR FURTHER INFORMATION CONTACT: Tenny P. Neprud, Regulations Policy Staff (HFC-10), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201 et seq., 52 Stat. 1040-1059, as amended, (21 U.S.C. 321 et seq.)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 16 is amended in § 16.1(b)(1) by adding the following:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * * Section 520(f)(2)(D) of the act relating to exemptions or variances from device good manufacturing practice requirements (see § 820.1(d)).

* * * * *

Effective date: February 15, 1980.

(Secs. 201 et seq. 52 Stat. 1040-1059 as amended (21 U.S.C. 321 et seq.))

Dated: February 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-4571 Filed 2-14-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification Dichlorophene Tablets; Dichlorophene and Toluene Capsules

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the regulations to reflect approval of a new animal drug application (NADA) filed by Happy Jack, Inc., providing for safe and effective use of dichlorophene tablets for treating dogs for certain helminth infections. The product is related to one reviewed by the National Academy of Sciences—National Research Council (NAS/NRC), Drug Efficacy Study Group, and found to be an effective anthelmintic. This document further amends the regulations to indicate those conditions of use for which approval of products that are identical, related, or similar to the NAS/NRC-reviewed product need not include certain types of efficacy data.

EFFECTIVE DATE: February 15, 1980.

FOR FURTHER INFORMATION CONTACT: Bob G. Griffith, 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: Happy Jack, Inc., Snow Hill, NC 28580, filed an NADA (7-829) providing for use of dichlorophene tablets in dogs as an aid in removing certain tapeworms. The dichlorophene tablets are related to the dichlorophene-toluene capsules that are the subject of the NAS/NRC evaluation published in the Federal Register of February 1, 1969 (34 FR 1612). In the evaluation, NAS/NRC concluded, and FDA concurred, that the dichlorophene component of the combination drug is effective as an aid in removing certain tapeworms from dogs and cats. Approval of the combination is reflected in § 520.580 (21 CFR 520.580). In this approval for Happy Jack's dichlorophene tablets, the conditions of use (dosage level, indications and limitations) in dogs are identical (except for absence of the claim for *Echinococcus sp.*) to those for the dichlorophene component of the NAS/NRC-reviewed drug. The firm submitted data from an animal study involving both products that demonstrate comparable effectiveness against tapeworms, (i.e., *T. pisiformis*) and therefore, bioequivalency. The firm also submitted data demonstrating that the product is safe.

The regulations are amended to editorially revise 21 CFR 520.580 to reflect current format, to add a new section to reflect this approval, and to specify those conditions of use for which approval of identical products need not include certain types of effectiveness data as specified by § 514.1(b)(8)(ii) or § 514.111(a) (5) (21 CFR 514.1(b)(8)(ii) or 514.111(a)(5)). In place of such data, approval of anthelmintics may require comparability or similar data.

In accordance with the provisions of Part 20 (21 CFR Part 20) promulgated under the Freedom of Information Act (5 U.S.C. 552) and the freedom of information regulations in § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is available for public examination at the office of the Hearing Clerk (HFA-305), Rm. 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) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended as follows:

1. By revising § 520.580 to read as follows:

§ 520.580 Dichlorophene and toluene capsules.

(a) *Specifications.* Each soft gelatin capsule contains 50 milligrams of dichlorophene and 60 milligrams of toluene or multiples thereof.[1]

(b) *Sponsor.* (1) For single dose only, see 000010, 000081, 000298, 000856, 010290, 011519, 011536, 011614, 015563, 017135, and 023851 in § 510.600(c) of this chapter.

(2) For single and multiple dose, see 000124, 000859, and 011716 in § 510.600(c) of this chapter.

(c) *Required statement.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of

[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.

parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use*—(1) *Amount.* (i) Single dose of 100 milligrams of dicholorophene and 120 milligrams of toluene per pound of body weight.[1]

(ii) Divided dose of 100 milligrams of dichlorophene and 120 milligrams of toluene per 5 pounds of body weight (20 and 24 milligrams per pound) daily for 6 days.[1]

(2) *Indications for use.* It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) and as an aid in removing tapeworms (*Taenia pisiformis, Dipylidium caninum,* and *Echinococcus granulosus*) from dogs and cats.[1]

(3) *Limitations.* Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward. Repeat treatment in 2 to 4 weeks in animals subject to reinfection.[1]

2. By adding new § 520.581 to read as follows:

§ 520.581 Dichlorophene tablets.

(a) *Specifications.* Each tablet contains 1 gram of dichlorophene.

(b) *Sponsor.* See 023851 in § 510.600(c) of this chapter.

(c) *Required statement.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use—Dogs*—(1) *Amount.* Single dose of 1 tablet (1 gram of dichlorophene) for each 10 pounds of body weight.

(2) *Indications for use.* It is used as an aid in the removal of tapeworms (*Taenia pisiformis* and *Dipylidium caninum*).

(3) *Limitations.* Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward.

Effective date. This amendment is effective February 15, 1980.

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

Dated: February 7, 1980.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 80-4893 Filed 2-14-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 520

Phenylbutazone Tablets; Revocation of Certain Regulations; Oral Dosage Form New Animal Drugs Not Subject to Certification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is revoking that portion of the regulations reflecting approval of a new animal drug application (NADA) providing for use of a phenylbutazone tablet in treating horses for certain inflammatory conditions associated with the musculoskeletal system. The sponsor, Norden Laboratories, requested the withdrawal of approval.

EFFECTIVE DATE: February 25, 1980.

FOR FURTHER INFORMATION CONTACT: Leonard D. Krinsky, Bureau of Veterinary Medicine (HFV-216), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, approval of NADA 102-823 is withdrawn. This document amends the regulations to delete that portion which reflects approval of this NADA.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director, Bureau of Veterinary Medicine (21 CFR 5.84), Part 520 is amended in § 520.1720a *Phenylbutazone tablets and boluses* by deleting in paragraph (b)(3) the number "011519."

Effective date: This amendment is effective February 25, 1980.

(Sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e)))

Dated: February 8, 1980.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 80-4892 Filed 2-14-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Parts 520 and 556

Deleting Claims for Use of Haloxon Drench in Sheep and Goats

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency amends the animal drug regulations to reflect approval of supplemental new animal drug applications (NADA's) filed by the Burroughs Wellcome Co. The supplements provide for deleting claims for use of haloxon drench in sheep and goats.

EFFECTIVE DATE: February 15, 1980.

FOR FURTHER INFORMATION CONTACT: David N. Scarr, 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 Burroughs Wellcome Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709, is the sponsor of NADA 48-913, approval for which is reflected in § 520.1120a. The section currently provides for use of haloxon drench as an anthelmintic in cattle, sheep, and goats.

The firm has filed supplements to NADA 48-913 that delete claims for use of the product in sheep and goats. The firm advised the agency that haloxon drench for use in sheep and goats would be discontinued and that the firm wished to support only the cattle claims for use of the product. The firm has provided final printed labeling deleting all indications for use of the product in sheep and goats and has agreed to appropriate revisions to § 520.1120a to delete provisions for use of haloxon drench in sheep and goats. Use of the product in sheep and goats will no longer be permitted.

In addition, § 556.310 is amended to delete reference to tolerances for use of this product in sheep and goats.

Under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; Dec. 23, 1977), the approval of these supplements does not expand use of the product. Thus, it poses no increased human risk from exposure to residues of the new animal drug and does not require reevaluation of the safety and effectiveness data in the parent application.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))), 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), Parts 520 and 556 are amended as follows:

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

1. Part 520 is amended in § 520.1120a by deleting and reserving paragraph (f)(2), as follows:

§ 520.1120a Haloxon drench.

* * * * *

(f) * * *

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

§ 556.310 [Amended]

2. Part 556 is amended in § 556.310 *Haloxon* by deleting the phrase "sheep,

and goats" and by placing a period after the work "cattle."

Effective date. February 15, 1980.

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

Dated: February 6, 1980.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 80-4572 Filed 2-14-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Parts 556 and 558

Reserpine; Revocation of Certain Regulations; New Animal Drugs for Use in Animal Feeds

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is revoking those regulations reflecting withdrawal of approval of a new animal drug application (NADA) sponsored by E. R. Squibb & Sons, Inc. The NADA provides for the use of Orticalm (reserpine) premix in complete turkey feed. This action has been requested by the sponsor.

EFFECTIVE DATE: February 25, 1980;

FOR FURTHER INFORMATION CONTACT: David N. Scarr, 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: Approval of NADA 11-581 is withdrawn in a notice issued elsewhere in this issue of the Federal Register. This document revokes the regulations which reflect withdrawal of approval of this NADA.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) 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 5.84), Parts 556 and 558 are amended as follows:

§ 556.570 [Revoked]

1. Part 556 is amended by revoking § 556.570 *Reserpine.*

§ 558.505 [Revoked]

2. Part 558 is amended by revoking § 558.505 *Reserpine.*

Effective date. This amendment is effective February 25, 1980.

(Sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e)))

Dated: February 8, 1980.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 80-4694 Filed 2-14-80; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 46 and 49

[T.D. 7665]

Removal of Statutory Sections From Title 26 of the Code of Federal Regulations; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction.

SUMMARY: This document corrects two typographical errors contained in T.D. 7665, 43 FR 6088, published in the Federal Register for January 25, 1980, which removed from Title 26 of the Code of Federal Regulations those regulation sections which recite verbatim provisions of the Internal Revenue Code of 1954.

EFFECTIVE DATE: The corrections to T.D. 7665 are effective January 25, 1980.

FOR FURTHER INFORMATION CONTACT: Jonathan P. Marget of the Employee Plans and Exempt Organizations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Ave., N.W., Washington, D.C. 20224, Attention: CC:LR:T (202-566-3651, not a toll-free call).

Correction of Regulations

Accordingly, FR Doc. 80-2361 (45 FR 6088) is amended by the following corrections on page 6091:

§ 46.0-1 [Corrected].

1. In column 1, line 26, "46.7420" is corrected to read "46.7240".

§ 49.0-1 [Corrected].

2. In column 2, line 28, "49.6264 (f)" is corrected to read "49.4264 (f)".

Dated: February 11, 1980.

George H. Jelly,

Director, Employee Plans and Exempt Organizations Division.

[FR Doc. 80-4876 Filed 2-14-80; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

Approved State Plans for Enforcement of State Standards; Approval of Supplements to Alaska State Plan

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Approval of Alaska supplements.

SUMMARY: This document gives notice of approval of five State plan changes which revise the Alaska Compliance Manual as well as of three State-initiated supplements to the Alaska plan. The compliance manual changes relate to (1) Contested Cases, (2) Denial of Entry, (3) Potential Exposure to Hazard(s), (4) Inspection of Private Employer Workplaces on Federal Government Property, (5) Imminent Danger, and Serious Violation Procedures for the Voluntary Compliance Program. The other three changes relate to (1) an Interagency agreement between the Alaska Department of Labor and the Alaska Department of Health and Social Services, (2) On-Site Consultation Agreement between the Alaska Department of Labor and the U.S. Department of Labor, Division of Occupational Safety and Health and (3) Reorganization of the Alaska Division of Occupational Safety and Health.

EFFECTIVE DATE: February 15, 1980.

FOR FURTHER INFORMATION CONTACT: Joseph C. Acton, Office of State Programs, Occupational Safety and Health Administration, Third and Constitution Avenue, NW., Washington, D.C. (202) 653-5377.

SUPPLEMENTARY INFORMATION:

Background

The Alaska Occupational Safety and Health Plan was approved under Section 18(c) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667(c)) (hereinafter referred to as the Act) and Part 1902 of this chapter on August 10, 1973 (38 FR 21628). Part 1953 of the Chapter provides procedures for the review and approval of State change supplements by the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter referred to as the Assistant Secretary).

Description of Supplements

A. *Contested Cases.* This State-initiated plan change is a revision to the