

designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701–1706; 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

2. Section 5.22 is amended by revising paragraphs (a)(1) through (a)(13) and by adding new paragraph (a)(14), by revising paragraphs (b)(1) and (b)(2), and by adding new paragraph (b)(3) to read as follows:

§ 5.22 Certification of true copies and use of Department seal.

- (a) * * *
- (1) The Deputy Commissioners.
 - (2) The Associate and Deputy Associate Commissioners.
 - (3)(i) The Director, Office of Executive Operations.
 - (ii) The Director, Executive Secretariat.
 - (iii) The Director, Program Management Staff.
 - (4) The Executive Assistant to the Commissioner, Office of the Commissioner.
 - (5)(i) The Director and Deputy Director, Office of Enforcement, Office of Regulatory Affairs (ORA).
 - (ii) The Director and Deputy Director, Office of Regional Operations, ORA.
 - (iii) The Director and Deputy Director, Office of Resource Management, ORA.
 - (iv) The Director, Division of Management Operations, and Chief, Administrative Management Branch, Office of Resource Management, ORA.

(v) The Director, FDA History Staff, ORA.

(6)(i) The Director, Division of Management Systems and Policy, Office of Management (OM).

(ii) The Chief, Dockets Management Branch, Division of Management Systems and Policy, OM.

(7) The Director, Freedom of Information Staff, Office of Public Affairs.

(8)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Director, Office of Management, CBER.

(iii) The Directors and Deputy Directors of the Office of Compliance, CBER.

(iv) The Director of Congressional and Public Affairs Staff, Office of the Center Director, CBER.

(v) The Chief, Surveillance and Policy Branch and Consumer Safety Officers, Office of Compliance, CBER.

(9)(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Management Systems, CFSAN.

(iv) The Director, Office of Cosmetics and Colors, CFSAN.

(v) The Director, Office of Plant and Dairy Foods Beverages, CFSAN.

(vi) The Director, Office of Seafood, CFSAN.

(vii) The Director, Office of Special Nutritional, CFSAN.

(viii) The Director, Office of Special Research Skills, CFSAN.

(ix) The Director, Office of Constituent Operations, CFSAN.

(x) The Director, Office of Field Programs, CFSAN.

(xi) The Director, Office of Premarket Approval, CFSAN.

(xii) The Director, Office of Scientific Analysis and Support, CFSAN.

(10)(i) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(ii) The Director, Office of Management Services, CDRH.

(iii) The Director and Deputy Director, Office of Compliance, CDRH.

(iv) The Director and Deputy Director, Division of Compliance Programs, CDRH.

(v) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

(11)(i) The Director and Deputy Directors, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Management, CVM.

(iii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iv) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(v) The Chief, Case Guidance Branch, Division of Compliance, Office of Surveillance and Compliance, CVM.

(12)(i) The Director and Deputy Director, National Center for Toxicological Research (NCTR).

(ii) The Director, Office of Research Support, NCTR.

(13)(i) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Management, Epidemiology and Biostatistics, Compliance, Drug Evaluation I, Drug Evaluation II, Research Resources, Generic Drugs, and Over-the-Counter Drug Evaluation, CDER.

(iii) The Chief and Freedom of Information Officers, Freedom of Information Staff, Office of Management, CDER.

(iv) The Director, Division of Management and Budget, Office of Management, CDER.

(v) The Directors of the Divisions of Drug Labeling Compliance, Drug Quality Evaluation, Manufacturing and Product Quality, and Scientific Investigations, Office of Compliance, CDER.

(14)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) The Director, St. Louis Branch.

(iv) The Director, New York Laboratory Division, Northeast Region.

(v) The Director, Southeast Regional Laboratory, Southeast Region.

(vi) The Director, National Forensic Chemistry Center.

(b) * * *

(1) Deputy Commissioners.

(2) The Associate and Deputy Associate Commissioners.

(3) The Director, Office of Human Resources Management, Office of Management.

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Dated: May 9, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–12398 Filed 5–18–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Chlortetracycline Soluble Powder Concentrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by the American Cyanamid Co. The supplemental NADA provides for the safe and effective use of chlortetracycline bisulfate (CTC bisulfate) soluble powder concentrate in the drinking water of chickens and turkeys for control of certain bacterial diseases susceptible to CTC, in the drinking water of swine, and as a drench in cattle for control and treatment of certain bacterial diseases susceptible to CTC. The approved supplemental NADA reflects compliance with findings of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group's (DESI) evaluation of related drug products' effectiveness and FDA's conclusions concerning that evaluation.

EFFECTIVE DATE: May 19, 1995.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1623.

SUPPLEMENTARY INFORMATION: American Cyanamid Co., Berdan Ave., Wayne, NJ 07470, is the sponsor of NADA 55-020 which provides for use of Aureomycin® CTC (bisulfate) Soluble Powder Concentrate (available in 1/4 and 10 pound packets) containing CTC bisulfate equivalent to 102.4 grams of CTC hydrochloride (CTC HCl) per pound. The drug product is used to medicate the drinking water of chickens, turkeys, swine, calves, beef cattle, and nonlactating dairy cattle in accordance with § 520.445b(d)(4) (21 CFR 520.445b(d)(4)). The NADA was originally approved on June 7, 1963.

American Cyanamid Co. filed a supplement to NADA 55-020 revising the product labeling to conform to that approved for the firm's supplemental NADA's 65-071 (Aureomycin® (CTC HCl) Soluble Powder) and 65-440 (Aureomycin® (CTC HCl) Soluble Powder Concentrate). Approval of those supplemental NADA's was published in the **Federal Register** of August 3, 1994 (59 FR 39438). The approval reflects compliance of the products' labeling with NAS/NRC findings and FDA's concurrence with those findings.

The NAS/NRC evaluation is concerned only with the drugs' effectiveness and safety to the treated animal. It does not take into account the safety for food use of food derived from

drug-treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drug or its metabolites in food products derived from treated animals.

Supplemental NADA 55-020 is approved as of April 6, 1995, and the regulations are amended by revising § 520.445b(d)(4) to reflect the approval. The basis for this approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 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 may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.445b is amended by revising paragraph (d)(4) introductory text to read as follows:

§ 520.445b Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate).

* * * * *

(d) * * *

(4) The following uses of chlortetracycline hydrochloride or chlortetracycline bisulfate in drinking water or drench were reviewed by the National Academy of Sciences/National Research Council (NAS/NRC) and found effective:

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Dated: May 4, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95-12291 Filed 5-18-95; 8:45 am]

BILLING CODE 4160-01-F

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1258

RIN 3095-AA63

Reproduction Services; Fee Schedule

AGENCY: National Archives and Records Administration (NARA).

ACTION: Final rule; confirmation of interim final rule.

SUMMARY: The National Archives and Records Administration (NARA) is adopting as a final rule the interim final rule on NARA reproduction fees. The interim rule corrected addresses and removed certain photographic reproductions and fees from the published fee schedule. This rule will affect Federal agencies and members of the public who order reproductions from NARA.

EFFECTIVE DATE: The effective date of this rule is March 6, 1995.

FOR FURTHER INFORMATION CONTACT: Mary Ann Hadyka or Nancy Allard on (301)713-6730.

SUPPLEMENTARY INFORMATION: On January 30, 1995, NARA issued an interim final rule. The effective date of the interim final rule was March 6, 1995. No comments were received during the 60-day comment period provided by the interim rule. Therefore, we are confirming in this final rule the correction of addresses and removal of published fees for certain reproductions in 36 CFR part 1258.

This rule is not a significant regulatory action for purposes of Executive Order 12866 of September 30,