Amendments to the Regulations

Accordingly, for the reasons stated in the preamble, Parts 12 and 178, Customs Regulations (19 CFR Parts 12 and 178), are amended as set forth below.

PART 12—SPECIAL CLASSES OF MERCHANDISE

1. The authority citation for Part 12 continues to read in part as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.118 through 12.127 also issued under 15 U.S.C. 2601 *et seq.*;

* * * * *

2. Section 12.121 is revised to read as follows:

§ 12.121 Reporting requirements.

(a) *Chemical substances in bulk or mixtures*—(1) *Certification required.* The importer of a chemical substance imported in bulk or as part of a mixture, or the authorized agent of such an importer, must certify either that the chemical shipment is subject to TSCA and complies with all applicable rules and orders thereunder, or that the chemical shipment is not subject to TSCA, by signing and filing with Customs one of the following statements:

I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order thereunder.

I certify that all chemical substances in this shipment are not subject to TSCA.

(2) *Filing of certification*—(i) *General.* The appropriate certification required under paragraph (a)(1) of this section must be filed with the director of the port of entry before release of the shipment and, except when a blanket certification is on file as provided for in paragraph (a)(2)(ii) of this section, must appear as a typed or stamped statement:

(A) On an appropriate entry document or commercial invoice or on an attachment to that entry document or invoice; or

(B) In the event of release under a special permit for an immediate delivery as provided for in § 142.21 of this chapter or in the case of an entry as provided for in § 142.3 of this chapter, on the commercial invoice or on an attachment to that invoice.

(ii) *Blanket certifications.* A port director may, in his discretion, approve an importer's use of a ''blanket'' certification, in lieu of filing a separate certification for each chemical shipment, for any chemical shipment that conforms to a product description provided to Customs pursuant to paragraph (a)(2)(ii)(A) of this section. In approving the use of a ''blanket'' certification, the port director should consider the reliability of the importer and Customs broker. Approval and use of a ''blanket'' certification will be subject to the following conditions:

(A) A ''blanket'' certification must be filed with the port director on the letterhead of the certifying firm, must list the products covered by name and Harmonized Tariff Schedule of the United States subheading number, must identify the foreign supplier by name and address, and must be signed by an authorized person;

(B) A ''blanket'' certification will remain valid, and may be used, for 1 year from the date of approval unless the approval is revoked earlier for cause by the port director. Separate ''blanket'' certifications must be approved and used for chemical substances that are subject to TSCA and for chemical substances that are not subject to TSCA; and

(C) An importer for whom the use of a ''blanket'' certification has been approved must include, on the invoice used in connection with the entry and entry summary procedures for each shipment covered by the ''blanket'' certification, a statement referring to the ''blanket'' certification and incorporating it by reference. This statement need not be signed.

(b) *Chemical substances or mixtures as parts of articles.* Each importer of a chemical substance or mixture as part of an article must comply with the certification requirements set forth in paragraph (a) of this section only if required to do so by a rule or order issued under TSCA.

(c) *Facsimile signatures.* The certification statements required under paragraph (a)(1) of this section may be signed by means of an authorized facsimile signature.

PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

1. The authority citation for Part 178 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

2. Section 178.2 is amended by adding a new listing to the table in numerical order to read as follows:

§ 178.2 Listing of OMB control numbers.

19 CFR section	Description	OMB control No.
* *	*	* *
§ 12.121	Approval of blanket certification under the Toxic Substances Control Act.	1515–0173
* *	*	* *

Raymond W. Kelly,

Commissioner of Customs.

Approved: December 7, 1999.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 00–4815 Filed 2–28–00; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for 13 new animal drug applications (NADA's) from I. D. Russell Co., Laboratories to Alpharma Inc.

DATES: This rule is effective February 29, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: I. D. Russell Co., Laboratories, 1301 Iowa Ave., Longmont, CO 80501, has informed FDA that it has transferred the ownership of, and all rights and interest in, the following approved NADA's to Alpharma Inc., One Executive Dr., Fort Lee, NJ 07024:

NADA No.	Product name
6–019	Zuco Poultry Tabs
6–081	Korum
6–776	10% Sulfaquinoxaline
6–860	Ruco Tablets
6–891	Liquid Sul-Q-Nox
8–902	Hepasol
100–094	Poultry Sulfa
100–175	20% Sulfaquinoxaline
100–176	34% Sulfaquinoxaline
130–435	Oxytet Soluble
200–106	R–Pen
200–189	Lincomycin Soluble
200–274	Lincomycin Injectable 30%

The agency is amending parts 510 and 520 (21 CFR parts 510 and 520) to reflect the change of sponsor. The agency is amending § 510.600(c)(1) and (c)(2) to remove the sponsor name for I. D. Russell Co., Laboratories because the firm no longer is the holder of any approved NADA's.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 520 are amended as follows:

PART 510 NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 *Names, addresses, and drug labeler codes* of sponsors of approved applications is amended in the table in paragraphs (c)(1) by removing the entry for ''I. D. Russell Co., Laboratories'' and in the table in paragraph (c)(2) by removing the entry for ''017144''.

PART 520 ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

§ 520.1263c [Amended]

4. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (b) by removing ''017144'' and adding in its place ''046573''.

§ 520.1660d [Amended]

5. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraphs (b)(2), (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*3*), (d)(1)(ii)(C)(*3*), and (d)(1)(iii)(C) by removing ''017144'' and adding in its place ''046573''.

§ 520.1696b [Amended]

6. Section 520.1696b *Penicillin G potassium in drinking water* is amended in paragraph (b) by removing ''017144,''.

§ 520.2088 [Amended]

7. Section 520.2088 *Roxarsone tablets* is amended in paragraph (c)(2) by removing ''017144'' and adding in its place ''046573''.

§ 520.2089 [Amended]

8. Section 520.2089 *Roxarsone liquid* is amended in paragraph (b) by removing ''017144'' and adding in its place ''046573''.

§ 520.2325a [Amended]

9. Section 520.2325a *Sulfaquinoxaline drinking water* is amended in paragraph (a)(3) by removing ''017144'' and adding in its place ''046573''.

Dated: February 16, 2000.

Claire M. Lathers,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Chlortetracycline Powder

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 Pennfield Oil Co. The supplemental NADA provides for a revised withdrawal time for use of chlortetracycline (CTC) powder in swine drinking water.

DATES: This rule is effective February 29, 2000.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, is sponsor of NADA 65–480 that provides for use of CTC hydrochloride soluble powder for making medicated drinking water for swine and cattle for treatment and control of bacterial enteritis and bacterial pneumonia. The firm filed a supplemental NADA that provides for a zero-day slaughter withdrawal period after use of the product for treatment