document meet the criteria for a ''significant regulatory action'' as specified in E.O. 12866.

List of Subjects in 19 CFR Part 12

Customs duties and inspection, Entry of merchandise, Imports, Prohibited merchandise, Restricted merchandise, Seizure and forfeiture.

Amendments to the Regulations

Part 12, Customs Regulations (19 CFR part 12), is amended as set forth below.

PART 12—SPECIAL CLASSES OF MERCHANDISE

1. The general authority citation for part 12 continues to read as follows, and the relevant specific sectional authority is revised to read 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 12.42 through 12.44 also issued under 19 U.S.C. 1307 and Pub. L. 105–61 (111 Stat. 1272);

* * * * *

2. Section 12.42 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 12.42 Findings of Commissioner of Customs.

(a) If any port director or other principal Customs officer has reason to believe that any class of merchandise that is being, or is likely to be, imported into the United States is being produced, whether by mining, manufacture, or other means, in any foreign locality with the use of convict labor, forced labor, or indentured labor under penal sanctions, including forced child labor or indentured child labor under penal sanctions, so as to come within the purview of section 307, Tariff Act of 1930, he shall communicate his belief to the Commissioner of Customs. * * *

* * * * *

3. Section 12.44 is revised to read as follows:

§ 12.44 Disposition.

(a) *Export and abandonment.* Merchandise detained pursuant to § 12.42(e) may be exported at any time prior to seizure pursuant to paragraph (b) of this section, or before it is deemed to have been abandoned as provided in this section, whichever occurs first. Provided no finding has been issued by the Commissioner of Customs under § 12.42(f) and the merchandise has not been exported within 3 months after the date of importation, the port director will ascertain whether the proof specified in § 12.43 has been submitted within the time prescribed in that section. If the proof has not been timely submitted, or if the Commissioner of Customs advises the port director that the proof furnished does not establish the admissibility of the merchandise, the port director will promptly advise the importer in writing that the merchandise is excluded from entry. Upon the expiration of 60 days after the delivery or mailing of such advice by the port director, the merchandise will be deemed to have been abandoned and will be destroyed, unless it has been exported or a protest has been filed as provided for in section 514, Tariff Act of 1930.

(b) *Seizure and summary forfeiture.* In the case of merchandise covered by a finding under § 12.42(f), if the Commissioner of Customs advises the port director that the proof furnished under § 12.43 does not establish the admissibility of the merchandise, or if no proof has been timely furnished, the port director shall seize the merchandise for violation of 19 U.S.C. 1307 and commence forfeiture proceedings pursuant to part 162, subpart E, of this chapter.

(c) *Prison-labor goods.* Nothing in this chapter precludes Customs from seizing for forfeiture merchandise imported in violation of 18 U.S.C. 1761 and 1762 concerning prison-labor goods.

Raymond W. Kelly,

Commissioner of Customs.

Approved: June 19, 2000.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 00–18819 Filed 7–25–00; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration, HHS

21 CFR Part 510

New Animal Drugs; Change of Sponsor Address

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor address for Wellmark International.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Norman Turner, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0214.

SUPPLEMENTARY INFORMATION: Wellmark International, 1000 Tower Rd., suite 245, Bensenville, IL 60106, has informed FDA of a change of sponsor address to 1100 East Woodfield Rd., suite 500, Schaumburg, IL 60173. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor address.

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 in 21 CFR Part 510

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

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 510 is 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 is amended in the table in paragraph (c)(1) by revising the entry for ''Wellmark International'' and in the table in paragraph (c)(2) by revising the entry for ''011536'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Wellmark International, 1100 East Woodfield Rd., suite 500, Schaumburg, IL 60173	011536
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
011536	Wellmark International, 1100 East Woodfield Rd., suite 500, Schaumburg, IL 60173
* * * * * * *	

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18824 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Sustained-Release Bolus

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 Merial Ltd. The supplemental NADA provides for changes to labeling of ivermectin sustained-release bolus for cattle.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, filed a supplement to NADA 140–988 that provides for use of Ivomec® (ivermectin) SR bolus for cattle. The supplement provides for reducing the predicted duration of effectiveness in labeling from approximately 135 days to approximately 130 days, based on bolus stability data. The supplement is approved as of June 21, 2000, and the regulations in 21 CFR 520.1197 are amended to reflect the approval. The basis of 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 the congressional review requirements in 5 U.S.C. 801–808.

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

§ 520.1197 [Amended]

2. Section 520.1197 *Ivermectin sustained-release bolus* is amended in paragraph (d)(2) by removing the parenthetical phrase ''(approximately 135 days)'' and by adding in its place '' (approximately 130 days)''.

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18827 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

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 a change of sponsor for 12 approved new animal drug applications (NADA's) from Merial Ltd. to Phoenix Scientific, Inc.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug