

associated with the musculoskeletal system.

**DATES:** This rule is effective July 10, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: [lluther@cvm.fda.gov](mailto:lluther@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724, filed ANADA 200-323 for the oral use of Phenylbutazone Tablets in horses for relief of inflammatory conditions associated with the musculoskeletal system. West-Ward Pharmaceutical's Phenylbutazone Tablets are approved as a generic copy of Boehringer Ingelheim Vetmedica's BIZOLIN (phenylbutazone) Tablets, approved under NADA 99-618. The ANADA is approved as of March 28, 2003, and the regulations are amended in 21 CFR 520.1720a to reflect the approval and current format. The basis of approval is discussed in the freedom of information summary.

In addition, West-Ward Pharmaceutical Corp., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR part 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.

FDA has determined under 21 CFR 25.33(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 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 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "West-Ward Pharmaceutical Corp." and in the table in paragraph (c)(2) by numerically adding a new entry for "000143" 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 |
| * * *   |  |  |  | * *               |
| West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724. |  |  |  | 000143            |
| * * *   |  |  |  | * *               |
| (2) * * *   |  |  |  |                   |
|   |  |  |  |                   |
| Drug labeler code   |  | Firm name and address  |  |                   |
| * *   |  | * * *  |  |                   |
| 000143  |  | West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724 |  |                   |
| * *   |  | * * *  |  |                   |

**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.

■ 4. Section 520.1720a is amended by adding paragraph (b)(5) to read as follows:

**§ 520.1720a Phenylbutazone tablets and boluses.**

\* \* \* \* \*

(b) \* \* \*

(5) No. 000143 for use of 1-gram tablets in horses.

\* \* \* \* \*

Dated: June 26, 2003.

**Andrew J. Beaulieu,**  
*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 03-17439 Filed 7-9-03; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Salinomycin, Chlortetracycline, and Roxarsone**

**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 an abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The ANADA provides for the use of single-ingredient Type A medicated articles containing salinomycin, chlortetracycline, and roxarsone to make three-way combination drug Type C medicated feeds for broiler chickens.

**DATES:** This rule is effective July 10, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: [lluther@cvm.fda.gov](mailto:lluther@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed ANADA 200-355 for use of PENNCHLOR (chlortetracycline), salinomycin, and roxarsone Type A medicated articles to make three-way combination drug Type C medicated feeds for broiler chickens. Pennfield Oil Co.'s ANADA 200-355 is approved as a generic copy of Alpharma, Inc.'s NADA 140-867. The ANADA is approved as of March 31, 2003, and the regulations are amended in 21 CFR 558.550 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 21 CFR part 20 and 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