between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**List of Subjects in 21 CFR Part 178**

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

## PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR Part 178 continues to read as follows:

**Authority**: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by revising the entry for ''Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester'' by adding item ''4.'' under the heading ''Limitations'' to read as follows:

**§ 178.2010 Antioxidants and/or stabilizers for polymers.**

* * * * *

(b) * * *

| Substances | Limitations |
|---|---|
| * * * | * * * * |
| Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester (CAS Reg. No. 161717–32–4), which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122–20–3). | For use only:<br>* * *<br>4. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1(a), 3.1(b), 3.1(c), 3.2 (a), or 3.2(b), having a density not less than 0.94 grams per cubic centimeter, in contact with foods only of types III, IV, V, VI–A, VI–C, VII, VIII, and IX identified in Table 1 of § 176.170(c) of this chapter, and under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter; provided that the food-contact surface does not exceed 0.003 inch (0.076 mm) in thickness. |
| * * * | * * * * |

Dated: June 23, 1998.

**L. Robert Lake,**

*Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.*

[FR Doc. 98–17544 Filed 7–1–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Parts 510 and 520

## Animal Drugs, Feeds, and Related Products; 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 two approved new animal drug applications (NADA's) from Danbury Pharmacal, Inc., to Phoenix Scientific, Inc.

**EFFECTIVE DATE:** July 2, 1998.

**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:** Danbury Pharmacal, Inc., 131 West St., Danbury, CT 06810, has informed FDA that it has transferred the ownership of and all rights and interests in the approved NADA's 91–818 and 94–170 (phenylbutazone tablets) to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457. The agency is amending 21 CFR 510.600(c)(1) and (c)(2) to remove the sponsor name for Danbury Pharmacal, Inc., because the firm no longer is the holder of any approved NADA's. The agency also is amending 21 CFR 520.1720a to reflect the change of sponsor.

**List of Subjects**

*21 CFR Part 510*

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

*21 CFR Parts 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.

**§ 510.600 [Amended]**

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Danbury Pharmacal, Inc.''; and in the table in paragraph (c)(2) by removing the entry for ''000591''.

## 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.

**§ 520.1720a [Amended]**

4. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(3) by removing the numbers ''000591, 000856, 000864, and 015579'' and adding in their place the numbers ''000856, 000864, 015579, and 059130''.

Dated: June 22, 1998.

**Margaret Ann Miller,**

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

[FR Doc. 98–17542 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 558

### New Animal Drugs For Use In Animal Feeds; Penicillin

**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 two supplemental new animal drug applications (NADA's), one filed by Alpharma Inc., the other by Pfizer, Inc. The supplemental NADA's provide for using approved penicillin G procaine Type A medicated articles to make Type C medicated chicken, turkey, pheasant, quail, and swine feeds used for increased rate of weight gain and improved feed efficiency.

**EFFECTIVE DATE:** July 2, 1998.

**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:** Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of NADA 46–666. Pfizer, Inc., 235 East 42d St., New York, NY 10017, is sponsor of NADA 46–668. The sponsors filed supplemental NADA's that provide for amending the regulations concerning use of penicillin Type A medicated articles to make Type B and C medicated feeds for chickens, turkeys, pheasants, quail, and swine for increased rate of weight gain and improved feed efficiency. The supplemental NADA's reflect the results of the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Implementation (DESI) review of the products' effectiveness and FDA's conclusions based on that review (35 FR 11533, July 17, 1970).

NAS/NRC evaluated these products as probably effective for faster gain and/or feed efficiency. FDA concurred with these findings and concluded that the appropriate claim should be ''for increased rate of weight gain and improved feed efficiency for (under appropriate conditions of use).'' The evaluation concerned only the drug's effectiveness and safety to the animal to which administered, and it did 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 drugs or their metabolites as residues in food products derived from treated animals.

In the **Federal Register** of August 30, 1977 (42 FR 43772), the then Bureau of Veterinary Medicine issued a notice of opportunity for hearing (NOOH) on a proposal to withdraw approval of NADA's for all penicillin-containing premixes (Type A medicated articles) intended for subtherapeutic use in animal feeds. The NOOH was issued in response to scientific research suggesting that subtherapeutic use of such drugs has contributed to the pool of antibiotic-resistant pathogenic microorganisms in food animals. Furthermore, research indicated that the drug resistance could be transferred to pathogenic organisms in humans. The NOOH is still pending and approval of these supplements to finalize the DESI review process for penicillin-containing Type A medicated articles does not constitute a bar to subsequent action to withdraw approval on the grounds cited in the outstanding NOOH.

The supplemental NADA's are approved as of April 10, 1998. The regulations are amended in 21 CFR 558.460 by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), by adding new paragraph (b), and by revising the table in paragraph (d) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 25.33(a)(3) 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.

**List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

2. Section 558.460 is amended by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), by adding paragraph (b), and by revising the table in paragraph (d)(1) to read as follows:

**§ 558.460 Penicillin.**

* * * * *

(b) *Sponsors.* Type A medicated articles: To 000069, 100 grams per pound. To 046573, 100 and 227 grams per pound.

* * * * *

(d) * * *

(1) * * *

| Penicillin in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|---|---|---|---|---|
| (i) 2.4 to 50 | | Chickens, turkeys, and pheasants; for increased rate of weight gain and improved feed efficiency. | Do not feed to poultry producing eggs for human consumption. | 000069, 046573. |
| (ii) 5 to 20 | | Quail; for increased rate of weight gain and improved feed efficiency. | Quail; not over 5 weeks of age. | Do. |