

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

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(c) * * *	
(1) * * *	
Firm name and address	Drug labeler code
* * *	* * *
Alpharma LLC, 400 Crossing Blvd., Bridgewater, NJ 08807.	046573
* * *	* * *
(2) * * *	
Drug labeler code	Firm name and address
* * *	* * *
046573	Alpharma LLC, 400 Crossing Blvd., Bridgewater, NJ 08807.
* * *	* * *

Dated: August 31, 2010.

Elizabeth Rettie,
Deputy 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 Parts 510 and 522

[Docket No. FDA-2010-N-0002]

New Animal Drugs; Change of Sponsor; Penicillin G Benzathine and Penicillin G Procaine Suspension; Penicillin G Procaine Aqueous Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two new animal drug applications (NADAs) from G. C. Hanford Manufacturing Co. to Norbrook Laboratories, Ltd.

DATES: This rule is effective September 3, 2010.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8307, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 65-493 for Penicillin G Procaine Aqueous Suspension and NADA 65-500 for Penicillin G Benzathine and Penicillin G Procaine Suspension, to Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland. Accordingly, the agency is amending the regulations in 21 CFR 522.1696a and 522.1696b to reflect the transfer of ownership.

In addition, FDA has noticed that “G. C. Hanford” and “GTC Biotherapeutics, Inc.” are not spelled correctly in the listing of sponsors of approved NADAs. At this time, the table in 21 CFR 510.600(c)(1) is amended. This action is being taken to improve the accuracy of the regulations.

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 522

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 522 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. In § 510.600, in the table in paragraph (c)(1), in the entry for “G. C. Biotherapeutics, Inc.”, remove “G. C.” and in its place add “GTC”; and in the entry for “GTC Hanford Manufacturing Co.”, remove “GTC” and in its place add “G. C.”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 4. In § 522.1696a, revise paragraphs (b)(1), (b)(2), (d)(2)(ii)(A), and (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(b) * * *

(1) Nos. 000856, 049185, 055529, and 061623 for use as in paragraph (d)(1) of this section.

(2) Nos. 055529, 059130, and 061623 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(A) Treatment of bacterial pneumonia (*Streptococcus* spp., *Actinomyces pyogenes*, *Staphylococcus aureus*); upper respiratory infections such as rhinitis or pharyngitis (*A. pyogenes*); blackleg (*Clostridium chauvoei*).

* * * * *

(iii) *Limitations.* Limit treatment to two doses. Not for use within 30 days of slaughter. For Nos. 049185, 055529, 059130, and 061623: A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

■ 5. In § 522.1696b, revise paragraphs (b)(1), (b)(2), (d)(2)(i)(A), and (d)(2)(iii)(B) to read as follows:

§ 522.1696b Penicillin G procaine aqueous suspension.

* * * * *

(b) * * *

(1) Nos. 053501, 055529, and 059130 for use as in paragraph (d) of this section.

(2) No. 061623 for use as in paragraph (d)(2) of this section.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(A) For Nos. 053501, 055529, 059130, and 061623: Continue treatment at least 48 hours after symptoms disappear.

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(iii) * * *

(B) For Nos. 055529 and 059130: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

Dated: August 31, 2010.

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

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