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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

[Docket No. FDA–2009–N–0665]

New Animal Drugs; Trilostane

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 original approval of a new animal drug application (NADA) filed by Dechra, Ltd. The NADA provides for the veterinary prescription use of trilostane capsules in dogs for treatment of pituitary-dependent hyperadrenocorticism and for treatment of hyperadrenocorticism due to adrenocortical tumor.

DATES: This rule is effective May 11, 2009.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom, filed NADA 141–291 that provides for veterinary prescription use of VETORYL (trilostane) Capsules in dogs for treatment of pituitary-dependent hyperadrenocorticism and for treatment of hyperadrenocorticism due to adrenocortical tumor. The NADA is approved as of December 5, 2008, and the regulations are amended in 21 CFR part 520 to reflect the approval.

In addition, Dechra, Ltd. is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this sponsor.

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 Division of Dockets Management (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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

Under section 573(c) of the act (21 U.S.C. 360ccc–2), the approval of trilostane capsules for treatment of hyperadrenocorticism due to adrenocortical tumor in dogs qualifies for 7 years of exclusive marketing rights beginning on the date of approval because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

The agency has determined under 21 CFR 25.33 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. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for ''Dechra, Ltd.''; and in the table in paragraph (c)(2), numerically add an entry for ''043264'' 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
* * *	* *
Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom	043264
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
043264	Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom
* *	* * *

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. Add § 520.2598 to read as follows:

§ 520.2598 Trilostane.

(a) *Specifications.* Each capsule contains 30 or 60 milligrams (mg) trilostane.

(b) *Sponsor.* See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* The starting dose is 1.0 to 3.0

milligrams per pound (2.2 to 6.7 milligrams per kilogram) once a day.

(2) *Indications for use.* For treatment of pituitary-dependent hyperadrenocorticism. For treatment of hyperadrenocorticism due to adrenocortical tumor.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 5, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–10927 Filed 5–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

[Docket No. FDA–2009–N–0665]

New Animal Drugs; Carprofen

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 the original approval of an abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The ANADA provides for the veterinary prescription use of carprofen caplets in dogs.

DATES: This rule is effective May 11, 2009.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed ANADA 200–498 that provides for veterinary prescription use of NOROCARP (carprofen) Caplets in dogs for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries. The ANADA is approved as of November 25, 2008, and the regulations are amended in 21 CFR 520.309 to reflect the approval.

In addition, FDA has found that a sponsor of another generic carprofen caplet product is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for IMPAX Laboratories, Inc.

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 Division of Dockets Management (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 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. In § 510.600, in the table in paragraph (c)(1) alphabetically add a new entry for ''IMPAX Laboratories, Inc.''; and in the table in paragraph (c)(2) numerically add a new entry for ''000115'' 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
* * *	* *
IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544	000115
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
000115	IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544
* *	* * *

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.

§ 520.309 [Amended]

■ 4. In paragraph (b)(2) of § 520.309, remove ''000115 and 062250'' and add in its place ''000115, 055529, and 062250''.

Dated: May 6, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–10925 Filed 5–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA–148–FOR; OSM–2008–0014]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule: clarification.

SUMMARY: We recently approved an amendment to the Pennsylvania regulatory program (the Pennsylvania program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The changes related to blasting for the development of shafts for underground mines and other changes to the blasting regulations in the Pennsylvania program. After our approval of the amendment, the Pennsylvania Department of Environmental Protection (PADEP) requested a clarification of our findings in support of that approval. Therefore,