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,

OSM is publishing a clarification of our previous findings.

DATES: *Effective Date:* May 11, 2009.

FOR FURTHER INFORMATION CONTACT: George Rieger, Director, Pittsburgh Field Division, Telephone: (717) 782–4036, e-mail: *grieger@osmre.gov.*

I. Background on the Pennsylvania Program
II. Prior Approval of the Amendment
III. Clarification of OSM's Finding in Support of the Decision
IV. Procedural Determinations

I. Background on the Pennsylvania Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''* * * a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Pennsylvania program on July 30, 1982. You can find background information on the Pennsylvania program, including the Secretary's findings, the disposition of comments, and conditions of approval in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions concerning Pennsylvania's program and program amendments at 30 CFR 938.11, 938.12, 938.13, 938.15 and 938.16.

II. Prior Approval of the Amendment

By letter dated June 8, 2006 (Administrative Record No. PA 887.00), PADEP sent OSM a program amendment to address blasting for the development of shafts for underground mines and to make administrative changes to regulations relating to blasting in 25 Pa. Code Chapters 77, 87, 88, 89 and 210.

OSM approved the amendment in a December 1, 2008, **Federal Register** notice (73 FR 72717). After publication of OSM's decision on the submitted amendment, PADEP contacted OSM requesting clarification of our characterization of the State's interpretation of 25 Pa. Code 87.127(a). In a letter dated December 17, 2008 (Administrative Record No. PA 887.15), PADEP stated the following:

> In OSM's finding relating to 25 Pa. Code 87.127(a), and the Federal counterpart at 30 CFR 817.61, the following statement is made: ''PADEP has determined that mine opening blasting conducted after the second blast is not subject to all of Pennsylvania's blasting regulations, because it is not blasting conducted pursuant to a surface coal mining operation, but rather is underground mine blasting * * *'' This statement is wrong. Pennsylvania has determined that mine opening blasting is *not* regulated as ''underground mine blasting.'' Rather the regulation created a new category of surface blasting, specifically identified as ''mine opening blasting.'' It *is* subject to all of Pennsylvania's surface mining blasting regulations, which specifically allow, that ''mine opening blasting conducted after the second blast, for that mine opening, may be conducted at any time of day or night * * *.''

PADEP specifically requested that OSM publish a clarification of this statement contained in our approval of the amendment in order to correct this error.

III. Clarification of OSM's Finding in Support of Our Decision

OSM's regulations apply to two categories of blasting: blasting associated with surface mining and surface blasting associated with underground mining. Our regulations at 30 CFR 817.61(a) specify that ''Sections 817.61–817.68 apply to surface blasting activities incident to underground coal mining, including, but not limited to, initial rounds of slopes and shafts.'' The definition of ''mine opening blasting'' as proposed by PADEP is ''* * * blasting conducted for the purpose of constructing a shaft, slope, drift, or tunnel mine opening for an underground mine * * *'' Based upon PADEP's definition, the requirements of 30 CFR 816.61–68, which regulate blasting at surface mining activities, do not apply. In addition, 30 CFR 817.61–68, regarding the regulation of surface blasting incident to underground coal mines, apply only to the initial rounds of slope and shaft development; blasting conducted subsequent to such activity (i.e. within the underground mine) is not regulated under these provisions. In our **Federal Register** notice announcing approval of the program amendment OSM stated that ''[w]e find that mine opening blasting after the second blast is indeed a reasonable point to terminate full regulatory coverage pursuant to 30 CFR 817.61–68.''

OSM understands that PADEP does not classify mine opening blasting as underground mine blasting, but rather as a ''new category of surface blasting.'' In addition, OSM understands that PADEP will continue to regulate mine opening blasting subsequent to the second blast in accordance with the language of the approved program amendment, as well as any other applicable provisions of the Pennsylvania Code. In effect, the ''new category of surface blasting'' that PADEP described, provides for the regulation of blasting, after the initial rounds of slope and shaft development, above and beyond that required by SMCRA and the corresponding Federal regulations. OSM recognized in its approval of the proposed amendment that PADEP was proposing to regulate mine opening blasting subsequent to the second blast, and our approval did nothing to limit or restrict the State's ability to do so. However, in order to alleviate the State's concerns about its interpretation of 25 Pa. Code 87.127(a), OSM is publishing this clarification.

This clarification of OSM's finding does not affect our decision to approve the Pennsylvania amendment as published in the **Federal Register** on December 1, 2008.

VI. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by Section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of Subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under Sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State

governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and Section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Government

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The basis for this determination is that our decision is on a State Regulatory program and does not involve a Federal regulation involving Indian Lands.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of Section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the Pennsylvania submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the Pennsylvania submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

Dated: February 9, 2009.

Thomas D. Shope,

Regional Director Appalachian Region.

[FR Doc. E9–10954 Filed 5–8–09; 8:45 am]

BILLING CODE 4310–05–P