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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Cefovecin

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 a new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for the veterinary prescription use of a solution of cefovecin sodium in cats and dogs by subcutaneous injection for the treatment of skin infections.

DATES: This rule is effective May 22, 2008.

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: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–285 that provides for the veterinary prescription use of CONVENIA (cefovecin sodium) Injectable in cats and dogs by subcutaneous injection for the treatment of skin infections. The application is approved as of April 25, 2008, and the regulations are amended in 21 CFR part 522 to reflect approval.

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 (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do 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 in 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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.311 [Redesignated as § 522.300]

■ 2. Redesignate § 522.311 as § 522.300.

§ 522.312 [Redesignated as § 522.304]

■ 3. Redesignate § 522.312 as § 522.304.

■ 4. Add new § 522.311 to read as follows:

§ 522.311 Cefovecin.

(a) *Specifications.* Each milliliter of constituted solution contains 80 milligrams (mg) cefovecin as the sodium salt.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 3.6 mg/pound (lb) (8 mg/kilograms (kg)) body weight as a single subcutaneous injection. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete.

(ii) *Indications for use.* For the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

(2) *Cats*—(i) *Amount.* Administer 3.6 mg/lb (8 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida*.

Dated: May 13, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–11515 Filed 5–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–275F]

RIN 1117–AA99

Changes to Patient Limitation for Dispensing or Prescribing Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment by Qualified Individual Practitioners

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: On September 20, 2007, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (72 FR 53734) proposing to conform its regulations to recent statutory amendments to the Controlled Substances Act that changed certain patient limitations for practitioners who dispense or prescribe certain narcotic drugs for maintenance or detoxification treatment. DEA received one comment in support of this rulemaking. DEA is finalizing the rule as proposed.

DATES: *Effective Date:* This rule is effective June 23, 2008.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Overview

On August 2, 2005, the President signed amendments to the Controlled Substances Act to increase the patient limitation on prescribing drug addiction treatments by qualified medical practitioners in group practices from 30 patients for each group to 30 patients for each qualified practitioner in a group (Pub. L. 109–56; 119 Stat. 591) (21 U.S.C. 823(g)(2)).

On December 29, 2006, the President signed amendments to the Controlled Substances Act to permit certain qualifying physicians to dispense and prescribe Schedule III, IV, and V narcotic controlled substances approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment to up to 100 patients at any one time, after the practitioner submits to the Secretary of Health and Human Services (HHS) a notification of the practitioner's need and intent to treat the increased number of patients. The amendment was made as part of the Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) (Section 1102 of Pub. L. 109–469, 120 Stat. 3502).

Notice of Proposed Rulemaking

On September 20, 2007 (72 FR 53734), DEA published a Notice of Proposed Rulemaking (NPRM) proposing to conform DEA regulations to Public Law 109–56 by removing the requirement in 21 CFR 1301.28(b)(iv) that limits to 30 the number of patients that could receive maintenance or detoxification treatment through a group practice. This change means that each qualifying practitioner whether working individually or in a group practice may offer maintenance and detoxification treatment to 30 patients at any one time. That NPRM also proposed to conform DEA regulations to Section 1102 of Public Law 109–469 by permitting certain qualifying physicians to treat up to 100 patients. As discussed in 21 U.S.C. 823(g)(2)(B) and (D) (and not modified by this rule), to be a ''qualifying physician'' the practitioner must submit to the Secretary of HHS notification of the practitioner's intent to begin dispensing the drugs approved by FDA specifically for maintenance or detoxification treatment. The notification must contain the following certifications:

- The practitioner is registered with DEA as an individual practitioner.
- The practitioner is a ''qualifying physician.'' A practitioner is a ''qualifying physician'' if he is licensed under State law and has specific medical certification, training, or experience in maintenance or detoxification treatment as specified in the CSA.
- With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.
- The total number of such patients of the practitioner at any one time will not exceed the applicable number. The applicable number is 30, unless, not sooner than one year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of HHS of the need and intent of the practitioner to treat up to 100 patients.
- The notification to the Secretary of HHS must be in writing and must state the name and DEA registration number of the practitioner.
- If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners.

As noted, certain qualifying physicians may treat up to 100 patients, instead of the thirty permitted for all qualifying physicians. To qualify to treat the additional patients, not sooner than one year after the practitioner submitted the initial notification, the practitioner must submit a second notification to the Secretary of HHS of the need and intent of the practitioner to treat up to 100 patients. Further, the practitioner must be a ''qualifying physician'' under 21 U.S.C. 823(g)(2)(G) as discussed above (21 CFR 1301.28(b)(1)(i) and (ii)). These amendments do not change the requirement that each practitioner must first qualify to prescribe and dispense these medications for maintenance and detoxification treatment, or must be prescribing these approved substances using the ''good faith'' exception, found within current regulations at 21 CFR 1301.28(e).

The ''good faith'' exception was established by the Drug Addiction Treatment Act of 2000, and is not affected by this Final Rule. The Controlled Substances Act (CSA) (21 U.S.C. 823(g)(2)(D)) states that not later than 45 days after the Secretary of HHS receives a notification discussed above, the Secretary shall make a determination of whether the practitioner meets all requirements for a waiver of the requirement of separate registration. Upon the expiration of the 45-day time period, a practitioner who in good faith submits a notification discussed above and reasonably believes that the conditions specified in 21 U.S.C. 823(g)(2)(B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver until notified otherwise by the Secretary of HHS. The practitioner may commence to prescribe or dispense such narcotic drugs for maintenance or detoxification treatment prior to the expiration of the 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

Background

On October 17, 2000, Congress passed the Drug Addiction Treatment Act of 2000 (DATA), amending the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*) to establish ''waiver authority for physicians who dispense or prescribe certain narcotic drugs for maintenance treatment or detoxification treatment'' (Pub. L. 106–310, title XXXV; 114 Stat. 1222, codified at 21 U.S.C. 823(g)(2)). Prior to DATA, the Controlled Substances Act and DEA regulations required practitioners who wanted to conduct maintenance or detoxification treatment using narcotic controlled drugs to be registered as a Narcotic Treatment Program (NTP) in addition to the practitioner's individual registration. The separate NTP registration authorized the practitioner to dispense or administer, but not prescribe, narcotic drugs.

With passage of DATA, DEA published a NPRM (68 FR 37429; June 24, 2003) proposing to amend the regulations affecting maintenance and detoxification treatment for narcotic treatment by establishing an exemption from the separate registration requirement. After consideration of the comments received on the NPRM, DEA published a Final Rule on June 23, 2005 (70 FR 36338). The June 23, 2005, Final Rule permitted the following:

(1) Qualifying physicians to dispense and prescribe Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration

specifically for use in maintenance or detoxification treatment.

(2) Narcotic-dependent patients to have one-on-one consultations with a practitioner in a private practice setting.

(3) Pharmacies to fill prescriptions for Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

(4) Practitioners to offer maintenance and detoxification treatment with Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to no more than 30 patients in their private practices without having a second registration as a NTP.

The exemption and other amendments established by the Final Rule apply to individual practitioners working in traditional NTPs as well as any other practice setting. The rule does not affect the existing prohibition against prescribing any Schedule II narcotic controlled drugs for maintenance or detoxification treatment.

Under the provisions of DATA implementing regulations as codified in 21 CFR 1301.28(b)(1)(iii) and (iv), the 30-patient limitation applied equally to individual practices and to group practices (i.e., 30 patients per group), severely limiting the number of patients that could be treated by physicians in group practices.

Pursuant to Public Law 109–56 effective on August 2, 2005, and Section 1102 of Public Law 109–469 effective on December 29, 2006, this Final Rule makes conforming changes to DEA's regulations at 21 CFR 1301.28(b)(1)(iii) and (iv). Specifically, paragraph (b)(1)(iii) is amended to permit the treatment of up to 100 patients by a qualifying practitioner if the necessary criteria are met (i.e., the practitioner previously was granted authority to dispense or prescribe Schedule III, IV, or V narcotic controlled drugs or combinations of narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment without being separately registered as a narcotic treatment program, and, not sooner than one year after the submission of the initial notification, the practitioner submits a second notification to the Secretary of HHS of the need and intent of the practitioner to treat up to 100 patients) and notification is submitted to the Secretary of Health and Human Services. Further, paragraph (b)(1)(iii) is amended by removing the phrase ''Where the individual practitioner is not a member of a group practice,'' since there is no longer a distinction between practitioners in group practices and those practicing independently. Finally, paragraph (b)(1)(iv) is deleted to remove language regarding members of group practices.

Relevant to the change regarding the treatment of up to 100 patients, the Director of the Center for Substance Abuse Treatment in the Department of Health and Human Services issued a letter announcing the statutory change as follows:

> Under ONDCPRA (effective December 29, 2006), physicians who meet the following criteria may notify the Secretary of Health and Human Services (HHS) of their need and intent to treat up to 100 patients at any time: (1) The physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify their capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DEA emphasizes that practitioners must meet these HHS criteria before prescribing a Schedule III, IV, or V controlled substance for narcotic maintenance or detoxification treatment to more than 30 patients at any one time.

Comments Received

DEA received one comment to its NPRM published September 20, 2007 at 72 FR 53734 from an association representing physicians. The commenter supported the rulemaking as proposed. The commenter strongly supported the proposed change to conform DEA regulations to the statutory changes made by Public Law 109–56, believing that the previous requirement limiting the number of patients who could receive treatment through a group practice to 30 was a barrier to treatment access. Further, the commenter supported the proposed change to conform DEA regulations to Section 1102 of Public Law 109–469, believing that the requirement for physicians to submit a supplemental notification to the Secretary of HHS of their need and intent to treat up to 100 patients, not sooner than one year after the practitioner submitted the initial notification, is ''a reasonable compromise at this time.'' Therefore, DEA is finalizing this rulemaking as proposed.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, has reviewed this regulation and hereby certifies that it has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) and that it will not have a significant economic impact on a substantial number of small entities. This rule relieves a restriction on practitioners desiring to treat narcotic dependent patients by removing the 30-patient limit for group practices and by permitting certain qualifying physicians to treat up to 100 patients after certain criteria are met. Thus, the changes provide greater access to care for patients due to increased patient limits.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rule has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is a significant regulatory action and, therefore, this action has been reviewed by the Office of Management and Budget. This rule will not impose additional costs on practitioners as it simply increases the number of patients that a practitioner may treat for narcotic dependence. As previously noted, this change provides greater access to care for patients due to the increased patient limits.

Executive Order 12988

This rule meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132

This rule does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have Federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

■ For the reasons set out above, 21 CFR part 1301 is amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957.

■ 2. Section 1301.28 is amended by revising paragraph (b)(1)(iii) and removing paragraph (b)(1)(iv) to read as follows:

§ 1301.28 Exemption from separate registration for practitioners dispensing or prescribing Schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

* * * * *

(b)(1) * * *

(iii) The total number of patients to whom the individual practitioner will provide narcotic drugs or combinations of narcotic drugs under this section will not exceed 30 at any one time unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification to the Secretary of Health and Human Services, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this subparagraph shall contain the certifications required by subparagraphs (i) and (ii) of this paragraph. The Secretary of Health and Human Services may promulgate regulations to change the total number of patients.

* * * * *

Dated: May 13, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. E8–11471 Filed 5–21–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2008–0339]

Drawbridge Operation Regulation; Illinois Waterway, Lockport, IL; Repair and Maintenance

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation governing the operation of the Elgin, Joliet, and Eastern Railroad Drawbridge, across the Illinois Waterway, Mile 290.1, at Lockport, Illinois. The deviation is necessary for the bridge to remain closed-to-navigation unless 1 hour advance notice is given. This deviation allows the bridge owner time to perform necessary repairs to the bridge.

DATES: This deviation is effective from 7 a.m. to 5 p.m., May 20, 2008, through June 2, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0339 and are available online at *http://www.regulations.gov*. They are also available for inspection or copying at two locations: The Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the Robert A. Young Federal Building, Room 2.107F, 1222 Spruce Street, St. Louis, MO 63103–2832, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Roger K. Wiebusch, Bridge Administrator, (314) 269–2378.

SUPPLEMENTARY INFORMATION: The Elgin, Joliet, and Eastern Railway requested a temporary deviation for the Elgin, Joliet, and Eastern Railroad Drawbridge, mile 290.1, at Lockport, Illinois across the Illinois Waterway to perform needed maintenance and repairs. The Elgin, Joliet, and Eastern Railroad Drawbridge currently operates in accordance with 33 CFR 117.393(d), which states the bridge is remotely operated and normally maintained in the open-to-navigation position, closing only to pass rail traffic and then reopening promptly for navigation. In order to facilitate the needed maintenance and repairs, the drawbridge must be kept in the closed-to-navigation position. This deviation allows for the bridge to remain closed-to-navigation unless 1 hour advance notice is given, from 7 a.m. to 5 p.m., May 20, 2008, through June 2, 2008.

There are no alternate routes for vessels transiting this section of the Illinois Waterway.

The Elgin, Joliet, and Eastern Railroad Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 24.6 feet above pool stage. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. This temporary deviation has been coordinated with waterway users. No objections were received.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: May 5, 2008.

Roger K. Wiebusch,

Bridge Administrator.

[FR Doc. E8–11441 Filed 5–21–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2008–0010]

RIN 1625–AA09

Drawbridge Operation Regulations; Mill Neck Creek, Oyster Bay, NY

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard has changed the drawbridge operation regulations that govern the operation of the Bayville Bridge, mile 0.1, across Mill Neck Creek at Oyster Bay, New York. This final rule will allow the bridge to open on signal between 7 a.m. and 11 p.m. from May 1 through October 31 and between 7 a.m. and 5 p.m., Monday through Friday, from November 1 through April 30. At all other times the bridge will open after a two-hour advance notice is