

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:

Orion Corp., Orionintie 1, 02200 Espoo, Finland, filed NADA 141-306 for veterinary prescription use of DORMOSEDAN GEL (detomidine hydrochloride) for sedation and restraint of horses. The application is approved as of March 22, 2010, and the regulations in 21 CFR part 529 are amended by adding new § 529.536 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of the safety and effectiveness data and information submitted to support approval of these applications 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.

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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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 529

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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 2. Add § 529.536 to read as follows:

§ 529.536 Detomidine.

(a) *Specifications.* Each milliliter of gel contains 7.6 milligrams (mg) of detomidine hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 0.018 mg per pound (mg/lb) (0.040 mg/kilogram (kg) sublingually.

(2) *Indications for use.* For sedation and restraint.

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

Dated: April 19, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010-9371 Filed 4-22-10; 8:45 am]

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DEPARTMENT OF JUSTICE**Bureau of Prisons****28 CFR Part 540**

[BOP-1149-I]

RIN 1120-AB49

Inmate Communication With News Media: Removal of Byline Regulations

AGENCY: Bureau of Prisons, Justice.

ACTION: Interim rule.

SUMMARY: In this interim rule, the Bureau of Prisons (Bureau) revises its regulations regarding inmate contact with the community to delete two current Bureau regulations that prohibit inmates from publishing under a byline, due to a recent court ruling invalidating Bureau regulation language containing this prohibition.

DATES: Comments are due by June 22, 2010.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT:

Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307-2105.

SUPPLEMENTARY INFORMATION:**Posting of Public Comments**

Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also locate all the personal identifying information you do not want posted online in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment contains so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on <http://www.regulations.gov>.

Personal identifying information identified and located as set forth above will be placed in the agency’s public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. If you wish to inspect the agency’s public docket file in person by appointment, *please see the FOR FURTHER INFORMATION CONTACT* paragraph.

In this interim rule, the Bureau revises its regulations regarding inmate contact with the community to delete two current Bureau regulations that prohibit inmates from publishing under a byline, due to a recent court ruling invalidating Bureau regulation language containing this prohibition.

Currently, 28 CFR 540.20(b) states as follows: “The inmate may not receive compensation or anything of value for correspondence with the news media. The inmate may not act as reporter or publish under a byline.”

Also, current 28 CFR 540.62(d) states as follows: “An inmate currently confined in an institution may not be employed or act as a reporter or publish under a byline.”

On August 9, 2007, in *Jordan v. Pugh*, 504 F.Supp.2d 1109 (D. Colo. 2007), the court issued a decision invalidating the byline language of § 540.20(b). The court found that not all inmate publishing under a byline jeopardizes security, and overruled the byline portion of the provision as facially overbroad for prohibiting all such activity. The Bureau is not appealing this decision. We

therefore alter the regulations accordingly.

Further, due to the court's findings regarding § 540.20(b), the identical provision in § 540.62(d) will also be deleted.

Administrative Procedure Act

The Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) allows exceptions to notice-and-comment rulemaking "when the agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." Further, § 553(d) provides an exception to the usual requirement of a delayed effective date when an agency finds "good cause" that the rule be made immediately effective.

This rulemaking is exempt from normal notice-and-comment procedures because advance notice and public comment in this instance is impracticable. It is impracticable to invite public comment on the result of a court order which invalidated the regulatory provision which we now seek to remove. Further, prompt implementation of the court order is necessary to protect the Bureau from liability arising from potential application of an invalidated regulation, and to afford inmates the benefit of the court's decision. Otherwise, this rulemaking makes no change to any rights or responsibilities of the agency or any regulated entities. For the same reasons, the Bureau finds that "good cause" exists to make this rule effective upon publication. Nevertheless, the Bureau invites public comment on this interim rule.

Executive Order 12866

This regulation falls within a category of actions that the Office of Management and Budget (OMB) has determined to constitute "significant regulatory actions" under section 3(f) of Executive Order 12866 and, accordingly, it was reviewed by OMB.

The Bureau of Prisons has assessed the costs and benefits of this regulation as required by Executive Order 12866 Section 1(b)(6) and has made a reasoned determination that the benefits of this regulation justify its costs. There will be no new costs associated with this regulation.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, under

Executive Order 13132, we determine that this regulation does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation and by approving it certifies that it will not have a significant economic impact upon a substantial number of small entities for the following reasons: This regulation pertains to the correctional management of offenders and immigration detainees committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by State, local and Tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it 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.

Small Business Regulatory Enforcement Fairness Act of 1996

This regulation is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This regulation 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 28 CFR Part 540

Prisoners.

Harley G. Lappin,

Director, Bureau of Prisons.

■ Under rulemaking authority vested in the Attorney General in 5 U.S.C 301; 28 U.S.C. 509, 510 and delegated to the Director, Bureau of Prisons amends 28 CFR part 540 as follows.

PART 540—CONTACT WITH PERSONS IN THE COMMUNITY

■ 1. Revise the authority citation for 28 CFR part 540 to read as follows:

Authority: 5 U.S.C. 301; 551, 552a; 18 U.S.C. 1791, 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses

committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

Subpart B—Correspondence

■ 2. Revise § 540.20(b) as follows:

§ 540.20 Inmate correspondence with representatives of the news media.

* * * * *

(b) The inmate may not receive compensation or anything of value for correspondence with the news media. The inmate may not act as reporter.

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Subpart E—Contact With News Media

■ 3. Revise § 540.62(d) as follows:

§ 540.62 Institutional visits.

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(d) An inmate currently confined in an institution may not be employed or act as a reporter.

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[FR Doc. 2010–9373 Filed 4–22–10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0256]

RIN 1625–AA00

Safety Zone; Neuse River, New Bern, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Neuse River in support of the New Bern, North Carolina Tercentennial Celebration. All vessels are prohibited from transiting the zone except as specifically authorized by the Captain of the Port or his designated representative. The temporary safety zone is necessary to provide for the safety of the crews, spectators, and other users and vessels of the waterway during a Civil War naval bombardment reenactment.

DATES: This rule is effective from 11:30 a.m. through 8 p.m. on May 8, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2010–0256 and are available online by going to <http://www.regulations.gov>, inserting USCG–2010–0256 in the "Keyword"