

matter to the USTR for Cabinet-level review as necessary.

(c) The USTR, after receiving the advice of the TPSC, TPRG, or Cabinet-level officials, shall make recommendations to the President on any proposed action to modify the application of the ATPA's benefits to countries or articles. The President (or if that function is delegated to the USTR, the USTR) shall announce in the **Federal Register** any such action he proposes to take. The USTR shall announce in the **Federal Register** notice of the results of the preliminary review, together with a schedule for receiving public input regarding such proposed action consistent with section 203(e) of the ATPA, as amended (19 U.S.C. 3202(e)).

(1) The schedule shall include the deadline and guidelines for any person to submit written comments supporting, opposing or otherwise commenting on any proposed action.

(2) The schedule shall also include the time and place of the public hearing, as well as the deadline and guidelines for submitting requests to present oral testimony.

(d) After receiving and considering public input, the Andean Subcommittee shall submit the results of the final review to the TPSC. The TPSC shall review the work of the Andean Subcommittee and shall conduct further review as necessary. The TPSC shall prepare recommendations for the President on any proposed action to modify the application of benefits under the ATPA to countries or articles. The Chairman of the TPSC may, as appropriate, convene the TPRG to review the matter, and thereafter refer the matter to the USTR for Cabinet-level review as necessary. The USTR, after receiving the advice of the TPSC, TPRG, or Cabinet-level officials, shall make recommendations to the President on any proposed action to modify the application of the ATPA's benefits to countries or articles, including recommendations that no action be taken. The USTR shall also forward to the President any documentation necessary to implement the recommended proposed action or actions to modify the application of the ATPA's benefits to countries or articles.

(e) In considering whether to recommend any proposed action to modify the ATPA, the Andean Subcommittee, on behalf of the TPSC, TPRG, or Cabinet-level officials, shall review all relevant information submitted in connection with a petition or otherwise available.

#### § 2016.2 Timetable for reviews.

Beginning in calendar year 2003, reviews of pending petitions shall be conducted at least once each year, according to the following schedule, unless otherwise specified by **Federal Register** notice:

- (a) September 15: Deadline for submission of petitions for review;
- (b) On or about December 1: Announcement published in the **Federal Register** of the results of preliminary review;
- (c) December/January: Written comments submitted and a public hearing held on any proposed actions;
- (d) February/March: Preparation of recommendations to the President, Presidential decision, and implementation of Presidential decision.

#### § 2016.3 Publication regarding requests.

Following the Presidential decision and where required, the publication of a Presidential proclamation modifying the application of benefits under the ATPA to countries or articles in the **Federal Register**, USTR will publish a summary of the decisions made in the **Federal Register**, including:

- (a) For petitions on which decisions were made, a description of the outcome of the review; and
- (b) A list of petitions on which no decision was made, and thus which are pending further review.

#### § 2016.4 Information open to public inspection.

With the exception of information subject to § 2016.5, any person may, on request, inspect in the USTR Reading Room:

- (a) Any written petition, comments, or other submission of information made pursuant to this part; and
- (b) Any stenographic record of any public hearings held pursuant to this part.

#### § 2016.5 Information exempt from public inspection.

(a) Information submitted in confidence shall be exempt from public inspection if USTR determines that the disclosure of such information is not required by law.

(b) A person requesting an exemption from public inspection for information submitted in writing shall clearly mark each page "BUSINESS CONFIDENTIAL" at the top, and shall submit a non-confidential summary of the confidential information. Such person shall also provide a written explanation of why the material should be so protected.

(c) A request for exemption of any particular information may be denied if

USTR determines that such information is not entitled to exemption under law. In the event of such a denial, the information will be returned to the person who submitted it, with a statement of the reasons for the denial.

**John K. Veroneau,**  
*General Counsel.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Phenylbutazone Paste

**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 an abbreviated new animal drug application (ANADA) filed by Bioniche Animal Health USA, Inc. The ANADA provides for oral use of phenylbutazone paste in horses for relief of inflammatory conditions associated with the musculoskeletal system.

**DATES:** This rule is effective July 25, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: [lluther@cvm.fda.gov](mailto:lluther@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601, filed ANADA 200-266 for the oral use of BUTEQUINE (phenylbutazone) Paste in horses for relief of inflammatory conditions associated with the musculoskeletal system. Bioniche Animal Health's BUTEQUINE Paste is approved as a generic copy of Schering-Plough Animal Health's PHENYLZONE (phenylbutazone) Paste, approved under NADA 116-087. The ANADA is approved as of February 21, 2003, and the regulations are amended in 21 CFR 520.1720c to reflect the approval and current format. The basis of approval is discussed in the freedom of information summary.

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 Dockets Management Branch (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(a)(1) 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 in 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 part 520 is amended as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Section 520.1720c is amended by revising paragraphs (a) and (b), by removing paragraph (c), and by redesignating paragraph (d) as new paragraph (c) to read as follows:

#### § 520.1720c Phenylbutazone paste.

(a) *Specifications*—(1) Each gram of paste contains 0.2 grams phenylbutazone.

(2) Each gram of paste contains 0.35 grams phenylbutazone.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 000061 and 010797 for use of product described in paragraph (a)(1) of this section.

(2) No. 064847 for use of product described in paragraph (a)(2) of this section.

\* \* \* \* \*

Dated: July 3, 2003.

**Andrew J. Beaulieu,**

*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 03-18910 Filed 7-24-03; 8:45 am]

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#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

#### 33 CFR Part 165

[CGD13-03-013]

RIN 1625-AA00

#### Safety Zone; Fireworks Display in the Captain of the Port Portland Zone, Colombia River, Astoria, OR

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of implementation of regulation.

**SUMMARY:** The Captain of the Port Portland will begin enforcing the safety zone for the Astoria Regatta Fireworks Display established by 33 CFR 165.1316 on July 17, 2003. The Captain of the Port, Portland, Oregon, is taking this action to safeguard watercraft and their occupants from safety hazards associated with the fireworks display. Entry into this safety zone is prohibited unless authorized by the Captain of the Port.

**DATES:** 33 CFR 165.1316 will be enforced August 9, 2003 from 9:30 p.m. until 10:30 p.m. (PDT).

**FOR FURTHER INFORMATION CONTACT:** Captain of the Port Portland, 6767 N. Basin Ave., Portland, OR 97217 at (503) 240-9370 to obtain information concerning enforcement of this rule.

**SUPPLEMENTARY INFORMATION:** On July 17, 2003, the Coast Guard published a final rule (68 FR 42289) establishing a safety zone, in 33 CFR 165.1316, to provide for the safety of vessels in the vicinity of the Astoria Regatta fireworks display. The safety zone will include all waters of the Columbia River at Astoria, Oregon enclosed by the following points: North from the Oregon shoreline at 123°49'36" West to 46°11'51" North thence east to 123°48'53" West thence south to the Oregon shoreline and finally westerly along the Oregon shoreline to the point of origin. Entry into this zone is prohibited unless authorized by the Captain of the Port or his designee. The Captain of the Port Portland will enforce this safety zone on August 9, 2003 from 9:30 p.m. until 10:30 p.m. (PDT). The Captain of the Port may be assisted by other Federal, state, or local agencies in enforcing this security zone.

Dated: July 9, 2003.

**Paul D. Jewell,**

*Captain, Coast Guard, Captain of the Port, Portland.*

[FR Doc. 03-18918 Filed 7-24-03; 8:45 am]

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#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

#### 33 CFR Part 165

[CGD09-03-399]

RIN 1625-AA00

#### Safety Zones; Captain of the Port Detroit Zone

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of implementation of regulation.

**SUMMARY:** The Coast Guard is implementing safety zones for annual fireworks displays in the Captain of the Port Detroit Zone during August 2003. This action is necessary to provide for the safety of life and property on navigable waters during these events. These zones will restrict vessel traffic from a portion of the Captain of the Port Detroit Zone.

**DATES:** Effective from 12:01 a.m. on August 1, 2003, to 11:59 p.m. on August 31, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Junior Grade Brandon Sullivan, U.S. Coast Guard Marine Safety Office Detroit, at (313) 568-9580.

#### SUPPLEMENTARY INFORMATION:

The Coast Guard is implementing the permanent safety zones in 33 CFR 165.907 (a)(22) and (23) (66 FR 27868, May 21, 2001), for fireworks displays in the Captain of the Port Detroit Zone during August 2003. The following safety zones are in effect for fireworks displays occurring in the month of August 2003:

(1) *Maritime Day Fireworks, Marine City, MI.* This safety zone will be enforced on August 9, 2003, from 8 p.m. until 11:59 p.m.

(2) *Venetian Festival Boat Parade & Fireworks, St. Clair Shores, MI.* This safety zone will be enforced on August 9, 2003, from 7 p.m. until 11:59 p.m.

In order to ensure the safety of spectators and transiting vessels, these safety zones will be enforced for the duration of the events. In cases where shipping is affected, commercial vessels may request permission from the Captain of the Port Detroit to transit the safety zone. Approval will be made on a case-by case basis. Requests must be made in advance and approved by the Captain of the Port Detroit before transits will be authorized. The Captain of the Port Detroit may be contacted via U.S. Coast Guard Group Detroit on Channel 16, VHF-FM.