

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.

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