4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2017-F-4399]

Food Additives Permitted in Feed and Drinking Water of Animals; Chromium DL-methionine Chelate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of chromium DL-methionine chelate as a nutritional source of chromium in cattle feed. This action is in response to a food additive petition filed by Zinpro Corp.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section V, Objections and Hearing Requests, for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the final amendment must be submitted by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to https://www.regulations.gov, will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on https://www.regulations.gov.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-F-4399 for "Food Additives Permitted in Feed and Drinking Water of Animals; Chromium DL-methionine Chelate." Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions,"

publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Wasima Wahid, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240-402-5857, Wasima.Wahid@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the *Federal Register* of September 22, 2017 (82 FR 44367), FDA announced that we had filed a food additive petition (animal use) (FAP 2300) submitted by Zinpro Corp., 10400 Viking Dr., Suite 240, Eden Prairie, MN 55344. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of chromium DL-methionine as a nutritional source of chromium in cattle feed.

II. Conclusion

FDA concludes that the data establishes the safety and utility of chromium DL-methionine chelate as a nutritional source of chromium in cattle feed and that the food additive regulations should be amended as set forth in this document. This final order is expected to result in expanded production options and is considered an E.O. 14192 deregulatory action.

The Agency found during review of the proposed use of the food additive that a different name for the substance better describes the additive. Additionally, to ensure consistency with the regulation for chromium propionate in 21 CFR 573.304 and due to the additive's composition being consistent with a chelate, the name of the additive is changed as indicated in the regulation. The proposed food additive name was changed from chromium DL-methionine in the notice of petition to chromium DL-methionine chelate in this final order.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

IV. Analysis of Environmental Impact

This action is categorically excluded under 21 CFR 25.32(r), for a substance that occurs naturally in the environment, when the action does not significantly alter the concentration or distribution of the substance, its metabolites, or degradation products in the environment. The proposed use of this substance falls within the categorical exclusion because chromium DL-methionine chelate completely dissociates into chromium and DL-methionine, both of which are naturally occurring compounds, and excretion of these compounds into the environment by cattle is not expected to significantly alter their concentration or distribution. The Agency is not aware of any extraordinary circumstances. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Add § 573.302, to subpart B, to read as follows:

§ 573.302 Chromium DL-methionine chelate.

The food additive, chromium DL-methionine chelate may be safely used as a nutritional source of chromium in cattle feed in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of a chromium salt with excess DL-methionine, at an appropriate stoichiometric ratio, to produce a chelate, tris (DL-methioninato) chromium (III) hydrochloride, and with the empirical formula $Cr[(CH_3S(CH_2)_2CH(NH_2)COO)_3]\cdot HCl$.

(b) The additive is added to complete feed for cattle at a level not to exceed 0.5 milligrams (mg) of chromium from chromium DL-methionine chelate per kilogram (kg) feed.

(c) The additive meets the following specifications:

(1) Total chromium content, 5 to 6 percent.

(2) Chelated chromium content, not less than 98 percent of the total chromium.

(3) Total DL-Methionine content, 80 to 85 percent.

(4) Hexavalent chromium content, less than 20 parts per million (ppm).

(5) Arsenic, less than 0.1 ppm.

(6) Cadmium, less than 0.05 ppm.

(7) Lead, less than 0.1 ppm.

(8) Mercury, less than 0.05 ppm.

(d) The additive shall be incorporated into feed as follows:

(1) It shall be incorporated into each ton of complete feed by adding no less than one pound of a premix containing no more than 453.6 milligrams of added chromium from chromium DL-methionine chelate per pound.

(2) Chromium from all sources of supplemental chromium cannot exceed a level of 0.5 ppm in complete feed for cattle.

(e) To assure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and feed shall contain the name of the additive.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) Minimum and maximum guarantees for added chromium content.

(ii) Adequate directions for use and cautions for use including this statement: “Caution: Follow label directions” and, consistent with the directions for use, the following: “Chromium from all sources of supplemental chromium cannot exceed 0.5 parts per million intake of the complete feed for cattle.”

(iii) Appropriate warnings and safety precautions concerning the chromium DL-methionine chelate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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