



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2014-F-1184]

Food Additives Permitted in Feed and Drinking Water of Animals; Selenium

AGENCY: Food and Drug Administration, Department of Health and Human Services (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 zinc L-selenomethionine as a source of selenium in complete feed for broiler chickens. 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-2014-F-1184 for "Food Additives Permitted in Feed and Drinking Water of Animals; Selenium." 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: Megan Hall, Center for Veterinary Medicine, Food and Drug Administration, 12225 Wilkins Ave., Rockville, MD 20852, 240-796-3801, Megan.Hall@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the *Federal Register* of August 21, 2014 (79 FR 49465), FDA announced that we had filed a food additive petition (animal use) (FAP 2285) 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 zinc L-selenomethionine as a source of selenium in complete feed for broiler chickens.

II. Conclusion

FDA concludes that the data establish the safety and utility of zinc L-selenomethionine as a source of selenium in complete feed for broiler chickens 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.

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

We have determined under 21 CFR 25.32(r) 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.

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. In § 573.920, revise paragraphs (a)(6) and (b) and add paragraph (i) to read as follows:

§ 573.920 Selenium.

(a) ***

(6) Paragraphs (b) through (i) of this section provide the currently acceptable levels of selenium supplementation.

(b) The food additive selenium is a nutrient administered in animal feed as sodium selenite or sodium selenate as provided in paragraph (c) of this section, as a controlled-release sodium selenite bolus as provided in paragraph (f) of this section, as selenium yeast as provided in paragraph (g) of this section, as selenomethionine hydroxy analogue as provided in paragraph (h)

of this section, or as zinc-L-selenomethionine complex as provided in paragraph (i) of this section.

(i) Zinc-L-selenomethionine complex [(2*S*)-2-amino-4-(methylseleno)butanoate zinc chloride], is manufactured by the reaction of a soluble zinc salt with chemically synthesized L-selenomethionine at an appropriate stoichiometric ratio. The additive is produced in liquid form and consists of not less than 19 percent (weight/weight) of L-selenomethionine.

- (1) The zinc-L-selenomethionine complex meets the following specifications:
 - (i) Arsenic, not more than 0.5 ppm;
 - (ii) Cadmium, not more than 1 ppm;
 - (iii) Lead, not more than 1 ppm; and
 - (iv) Mercury, not more than 0.1 ppm.
- (2) Selenium, as zinc-L-selenomethionine complex, is added to complete feed for broiler chickens at a level not to exceed 0.3 ppm.
- (3) The additive, as zinc L-selenomethionine complex, shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.
- (4) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of zinc-L-selenomethionine complex in its packaged form shall contain:
 - (i) The name of the additive, zinc-L-selenomethionine complex;
 - (ii) Minimum and maximum guarantees for total selenium;
 - (iii) Minimum guarantee for selenomethionine content;
 - (iv) The following statement, “Storage Conditions: zinc-L-selenomethionine complex must be stored in a closed package at temperature not higher than 25 °C (77 °F).”; and

(v) An expiration date not to exceed 6 months from the date of manufacture.

(5) Usage of this additive must conform to the requirements of paragraphs (d) and (e) of this section.

Dated: May 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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