4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2018-F-3347]

Food Additives Permitted in Feed and Drinking Water of Animals; Chromium Propionate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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 propionate as a source of supplemental chromium in horse feed. This action is in response to a food additive petition filed by Kemin Industries, Inc.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section V of this document for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule 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. Electronic objections must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 postmarked or the delivery service acceptance receipt is 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-2018-F-3347 for "Food Additives Permitted in Feed and Drinking Water of Animals; Chromium Propionate." 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.

- 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 objections 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.

FOR FURTHER INFORMATION CONTACT: Chelsea Cerrito, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-224), Rockville, MD 20855, 240-402-6729, Chelsea.Cerrito@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the *Federal Register* of October 2, 2018 (83 FR 49508), FDA announced that we had filed a food additive petition (animal use) (FAP 2306) submitted by Kemin Industries, Inc., 1900 Scott Ave., Des Moines, IA 50317. 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 propionate as a source of supplemental chromium in horse feed.

II. Conclusion

FDA concludes that the data establish the safety and utility of chromium propionate as a source of supplemental chromium in horse feed and that the food additive regulations should be amended as set forth in this document.

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

The Agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see ADDRESSES) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and

analysis for any particular objection shall constitute a waiver of 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 § 573.304, revise paragraphs (b), (c), (d)(3), and (e)(2)(ii) to read as follows:

§ 573.304 Chromium propionate.

* * * * *

(b) The additive is added to feed as follows:

(1) In complete feed for broiler chickens at a level not to exceed 0.2 milligrams (mg) of chromium from chromium propionate per kilogram feed.

(2) In feed for horses at a level not to exceed an intake of 4 mg of chromium from chromium propionate per horse per day.

(c) The additive meets the following specifications:

(1) Total chromium content, 8 to 10 percent.

(2) Hexavalent chromium content, less than 2 parts per million (ppm).

(3) Arsenic, less than 1 ppm.

(4) Cadmium, less than 1 ppm.

(5) Lead, less than 0.5 ppm.

(6) Mercury, less than 0.5 ppm.

(7) Viscosity, not more than 2,000 centipoise.

(d) * * *

(3) Chromium from all sources of supplemental chromium cannot exceed:

(i) A level of 0.2 ppm in complete feed for broiler chickens.

(ii) An intake of 4 mg per horse per day.

(e) * * *

(2) * * *

(ii) Adequate directions for use and cautions for use including these statements: "Caution: Follow label directions" and consistent with the directions for use, the following:

(A) For feed for broiler chickens, "Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed for broiler chickens."

(B) For feed for horses, "Chromium from all sources of supplemental chromium cannot exceed 4 milligrams per horse per day."

Dated: March 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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