DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2014–F–0232]

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 chromium in broiler chicken feed. This action is in response to a food additive petition filed by Kemin Industries, Inc.

DATES: This rule is effective June 3, 2016. Submit either written or electronic objections and requests for a hearing by July 5, 2016. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit comments or written objections and a request for a hearing as follows:

Electronic Submissions

Submit electronic comments/objections in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments/objections submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment/objection will be made public, you are solely responsible for ensuring that your comment/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 comments/objection, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment/objection with confidential information that you do not wish to be made available to the public, submit the comment/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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments/objections submitted to the Division of Dockets Management, FDA will post your comment, 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–0232 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Chromium Propionate.'' Received comments/objections will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment/objection with confidential information that you do not wish to be made publicly available, submit your comments/objections only as a written/paper submission. You should submit two copies 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 comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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 comments 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6729, *chelsea.trull@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of March 10, 2014 (79 FR 13263), FDA announced that we had filed a food additive petition (animal use) (FAP 2282) submitted by Kemin Industries, Inc., 2100 Maury St., Des Moines, IA 50317. The petition proposed to amend the food additive regulations to provide for the safe use of chromium propionate as a source of chromium in broiler chicken feed. The notice of petition was subsequently corrected to indicate the submission of an environmental assessment by the petitioner (79 FR 38478, July 8, 2014).

II. Conclusion

FDA concludes that the data establish the safety and utility of chromium propionate for use as proposed 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 Division of Dockets Management (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 Division of Dockets Management (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.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

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 and redelegated to the Center for Veterinary Medicine, 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 § 573.304 to read as follows:

§ 573.304 Chromium Propionate.

The food additive chromium propionate may be safely used in animal feed as a source of supplemental chromium in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of a chromium salt with propionic acid, at an appropriate stoichiometric ratio, to produce triaqua-(mu_3-oxo) hexakis (mu_2-propionato-*O,O*′) trichromium propionate with the empirical formula, $[Cr_3(O)(CH_3CH_2CO_2)_6(H_2O)_3]$ $CH_3CH_2CO_2$.

(b) The additive shall be incorporated at a level not to exceed 0.2 milligrams of chromium from chromium propionate per kilogram feed in broiler chicken complete feed.

(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.

(3) Arsenic, less than 1 part per million.

(4) Cadmium, less than 1 part per million.

(5) Lead, less than 0.5 part per million.

(6) Mercury, less than 0.5 part per million.

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

(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 181.4 milligrams of added chromium from chromium propionate per pound.

(2) The premix manufacturer shall follow good manufacturing practices in the production of chromium propionate premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production.

(3) Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed.

(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 complete feed shall contain the name of the additive.

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

(i) A guarantee for added chromium content.

(ii) Adequate directions for use and cautions for use including this statement: Caution: Follow label directions. Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed.

Dated: May 26, 2016.

Tracey Forfa,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2016–13082 Filed 6–2–16; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 120, 123, 124, 125, and 126

[Public Notice: 9487]

RIN 1400–AD70

International Traffic in Arms: Revisions to Definition of Export and Related Definitions

AGENCY: Department of State.

ACTION: Interim final rule.

SUMMARY: As part of the President's Export Control Reform (ECR) initiative, the Department of State amends the International Traffic in Arms Regulations (ITAR) to update the definitions of ''export,'' and ''reexport or retransfer'' in order to continue the process of harmonizing the definitions with the corresponding terms in the Export Administration Regulations (EAR), to the extent appropriate. Additionally, the Department creates definitions of ''release'' and ''retransfer'' in order to clarify and support the interpretation of the revised definitions that are in this rulemaking. The Department creates new sections of the ITAR detailing the scope of licenses, unauthorized releases of controlled information and revises the section on ''exports'' of technical data to U.S. persons abroad. Finally, the Department consolidates regulatory provisions on the treatment of foreign dual and third country national employees within one exemption.

DATES: The rule is effective on September 1, 2016. The Department of State will accept comments on this interim final rule until July 5, 2016.

ADDRESSES: Interested parties may submit comments within 30 days of the date of publication by one of the following methods:

- *Email: DDTCPublicComments@state.gov* with the subject line, ''ITAR Amendment—Final Revisions to Definitions.''
- *Internet:* At *www.regulations.gov,* search for this notice by using this rule's RIN (1400–AD70).

Comments received after that date may be considered, but consideration cannot be assured. Those submitting comments should not include any personally identifying information they