DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2019–F–3911]

Food Additives Permitted in Feed and Drinking Water of Animals; Silicon Dioxide

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 silicon dioxide as an anticaking agent, grinding aid, antifoaming agent, or carrier in animal feed components (ingredients, intermediate premixes, premixes, supplements, or concentrates). This action is in response to a food additive petition filed by Evonik Corp.

DATES: This rule is effective June 2, 2020. 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 July 2, 2020.

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 July 2, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 2, 2020. 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–2019–F–3911 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Silicon Dioxide.'' 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 1, 2019 (84 FR 52055), FDA announced that we had filed a food additive petition (animal use) (FAP 2308) submitted by Evonik Corp., 1707 Barrett Lakes Blvd. NW, Suite 340, Kennesaw, GA 30144. 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 silicon dioxide as an anticaking agent, grinding aid, antifoaming agent, or carrier in animal feed components (ingredients, intermediate premixes, premixes, supplements, or concentrates). This amendment to the regulation approves the use of the food additive for these technical uses across food substances.

II. Conclusion

FDA concludes that the data establish the safety and utility of silicon dioxide as an anticaking agent, grinding aid, antifoaming agent, or carrier in animal feed components (ingredients, intermediate premixes, premixes, supplements, or concentrates) 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

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

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 § 573.940, revise paragraphs (b) through (e) to read as follows:

§ 573.940 Silicon dioxide.

* * * * *

(b) It is used or intended for use as an anticaking agent, antifoaming agent, carrier, and/or grinding aid in animal feed, including ingredients, intermediate premixes, premixes, supplements, concentrates, and complete feed.

(c) To ensure safe use of the additive, silicon dioxide is to be used in an amount not to exceed that reasonably required to accomplish its intended effect, and silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.

(d) To ensure safe use of the additive, the label and labeling of the additive and ingredients, intermediate premixes, premixes, supplements, concentrates, and complete feed containing the additive shall meet the requirements of the Federal Food, Drug, and Cosmetic Act, including part 501 of this chapter.

(e) To ensure 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 the additive and ingredients, intermediate premixes, premixes, supplements, and concentrates containing the additive shall have:

(1) A statement of the concentration of the additive.

(2) A statement that silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10033 Filed 6–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 18, 19, 24, 25, 26, 27, 28, 30, and 70

[Docket No. TTB–2016–0013; T.D. TTB–159; Re: T.D. TTB–146; Notice No. 167]

RIN 1513–AC30

Changes to Certain Alcohol-Related Regulations Governing Bond Requirements and Tax Return Filing Periods

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is adopting as final, with minor technical corrections, temporary regulations relating to excise taxes imposed on distilled spirits, wines, and beer that were published in the **Federal Register** on January 4, 2017. These regulatory amendments implement certain changes made to the Internal Revenue Code of 1986 (IRC) by the Protecting Americans from Tax Hikes Act of 2015, which amended the IRC to remove bond requirements and change tax return due dates for certain eligible excise taxpayers.

DATES: This final rule is effective June 2, 2020. As of June 2, 2020, the temporary regulations published in the **Federal Register** as T.D. TTB–146 at 82 FR 1108 on January 4, 2017, at 82 FR 1108, are adopted as final.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW, Box 12, Washington, DC 20005; telephone 202–453–2265, ext. 175.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers provisions in chapter 51 of the IRC pertaining to the taxation of distilled spirits, wines, and beer (see title 26 of the United States Code (U.S.C.), chapter 51 (26 U.S.C. chapter 51)). The IRC also contains provisions requiring certain persons who are liable for taxes imposed with respect to distilled spirits, wines, and beer to furnish bonds, which are formal guarantees to pay tax obligations under the IRC (see, *e.g.,* 26 U.S.C. 5173, 5354, and 5401(b)). TTB administers the provisions of the IRC, and their implementing regulations, pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013 (superseding Treasury Department Order 120–01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in administration and enforcement of these provisions of law.

The PATH Act

On December 18, 2015, the President signed into law the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Division Q of this Act is titled the Protecting Americans from Tax Hikes Act of 2015 (PATH Act). Section 332 of the PATH Act amends the IRC to change tax return due dates and remove bond requirements for certain eligible taxpayers beginning January 1, 2017. These PATH Act amendments apply to certain taxpayers who reasonably expect to be liable for not more than $50,000 in taxes imposed with respect to distilled spirits, wines, and beer for the calendar year and who were not liable for more than $50,000 in such taxes in the preceding calendar year.