The Food and Drug Administration (FDA), in accordance with section 409 of the Food, Drug, and Cosmetic Act (21 U.S.C. 349), is amending regulations for food additives permitted in feed and drinking water of animals; in response to a food additive petition filed by Idemitsu Kosan, Ltd.

(Summary)

This rule is effective March 2, 2018. See section V of this document for the safe use of silicon dioxide as a carrier for flavors. This action is in response to a food additive petition filed by Idemitsu Kosan, Ltd.

(Dates)

This rule is effective March 2, 2018. See section V of this document for information on the filing of objections. Submit either electronic or written objections and requests for a hearing as follows.

Address:

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.

Electronic Submissions

Submit electronic objections in the following way:

2. Objected 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.

Write/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–5528 for “Food Additives Permitted in Feed and Drinking Water of Animals; Silicon Dioxide as a Carrier for Flavors.” Under “Instructions,” 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 include the Docket No. FDA– 2017–F–5528 for “Food Additives Permitted in Feed and Drinking Water of Animals; Silicon Dioxide as a Carrier for Flavors.” Under “Instructions,” 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 April 2, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of April 2, 2018. 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.

Addressees:

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 April 2, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of April 2, 2018. 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.

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II. Conclusion

The petition proposed that the regulations should be amended as set forth in this document. This is not a significant regulatory action subject to Executive Order 12666.

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 inspection at the Center for Veterinary Medicine by appointment with the information contact person (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 before making the documents available for inspection.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.32(e) 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.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at https://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, 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:


2. In § 573.940, add paragraphs (d) and (e) to read as follows:

§ 573.940 Silicon dioxide.

* * * * *

(d) It is used or intended for use in feed components, as a carrier as follows:

<table>
<thead>
<tr>
<th>Feed component</th>
<th>Limitations (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flavors</td>
<td>50</td>
</tr>
</tbody>
</table>

(e) 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.


Leslie Kux,
Associate Commissioner for Policy.

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