

the filing does not include a subsequent interim period that also reflects application of this guidance, then the staff expects it to be applied retrospectively to the beginning of the two most recent annual periods ending before June 15, 2022.

For all entities, in the financial statements that reflect the initial application of this guidance, the effect of the initial application should be reported in the carrying amounts of assets and liabilities as of the beginning of the annual period specified above. Entities should include clear disclosure of the effects of the initial application of this guidance.<sup>15</sup>

[FR Doc. 2022-07196 Filed 4-8-22; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 573

[Docket No. FDA-2011-F-0365]

#### Food Additives Permitted in Feed and Drinking Water of Animals; Methyl Esters of Conjugated Linoleic Acid

**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 methyl esters of conjugated linoleic acid for early lactation dairy cows to reduce the energy concentration in milk. This action is in response to a food additive petition filed by BASF Corp.

**DATES:** This rule is effective April 11, 2022. 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 May 11, 2022.

**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 May 11, 2022. The <https://www.regulations.gov> electronic filing

system will accept objections until 11:59 p.m. Eastern Time at the end of May 11, 2022. 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-2011-F-0365 for "Food Additives Permitted in Feed and Drinking Water of Animals; Methyl Esters of Conjugated Linoleic Acid; 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, 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 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, 240-402-7500.

#### FOR FURTHER INFORMATION CONTACT:

Megan Hall, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-221), Rockville, MD 20855, 301-796-3801, [Megan.Hall@fda.hhs.gov](mailto:Megan.Hall@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In a document published in the **Federal Register** of June 6, 2011 (76 FR 32332), FDA announced that we had filed a food additive petition (animal use) (FAP 2269) submitted by BASF Corp., 100 Campus Dr., Florham Park, NJ 07932. The petition proposed that the regulations for food additives permitted in feed and drinking water of

for the nine months ended September 30, 2022 would apply the SAB to those periods.

<sup>15</sup> For U.S. GAAP, see FASB ASC 250-10-50-1 through 50-3; for IFRS, see IAS 8. See also, e.g., Item 302 of Regulation S-K and PCAOB Auditing Standard 2820 (par. 8).

animals be amended to provide for the safe use of methyl esters of conjugated linoleic acid as a source of fatty acids in lactating dairy cow diets and for the use of silicon dioxide as a carrier for the methyl esters of conjugated linoleic acid.

In 2020, 21 CFR 573.940 was 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) across food substances under FAP 2308 (85 FR 33539, June 2, 2020).

## II. Conclusion

FDA concludes that the data establish the safety and utility of methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) for early lactation dairy cows to reduce the energy concentration in milk, 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 § 573.637, revise the introductory text and paragraph (b) to read as follows:

#### § 573.637 Methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids).

The food additive, methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids) may be safely used in swine feed and feed for early lactation dairy cows (less than 100 days in milk) in accordance with the prescribed conditions:

\* \* \* \* \*

(b) The additive is used or intended for use in the feed of:

(1) Growing and finishing swine as a source of fatty acids at levels not to exceed 0.6% in the finished feed.

(2) Early lactation dairy cows to reduce the energy concentration in milk when fed at levels not to exceed 33 grams per cow per day.

\* \* \* \* \*

Dated: April 4, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–07680 Filed 4–8–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Parts 1301, 1309, and 1321

[Docket No. DEA–587]

RIN 1117–AB58

#### Requiring Online Submission of Applications for and Renewals of DEA Registration

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This rulemaking amends the Drug Enforcement Administration's (DEA) regulations to now require all applications for DEA registrations, and renewal of those registrations, to be submitted online.

**DATES:** This final rule is effective May 11, 2022.

#### FOR FURTHER INFORMATION CONTACT:

Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (571) 776–2265.

#### SUPPLEMENTARY INFORMATION:

#### Legal Authority

The Drug Enforcement Administration (DEA) has the legal authority to amend its regulations to require online applications pursuant to the Controlled Substances Act (CSA). The CSA grants the Attorney General authority to promulgate rules and regulations relating to: The registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals; reporting changes to professional or business addresses; and the efficient execution of his statutory functions. 21 U.S.C. 821, 822(a), 827(h), 871(b), 957(a). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances and listed chemicals. 21 U.S.C. 958(f). The Attorney General has delegated this authority to the Administrator of DEA. 28 CFR 0.100(b).

#### Need for Regulatory Changes

Regulatory changes are needed to modernize DEA's approach to registration and renewal applications. The proposed changes require online submission and eliminate inefficient paper applications. Typographical errors or missing pieces of information routinely resulted in delayed or rejected applications. DEA has determined the