are an ''agency's reading of a statute'' that do not ''intend to create new rights or duties, but only remind affected parties of existing duties.'' [16]

28. This final rule is an interpretive rule because it modifies the Commission's regulations to conform to the Water Infrastructure Act. It does not create new rights or duties. Rather, it reminds affected parties of existing duties required by the Water Infrastructure Act, with which the Commission and non-agency entities have complied since the Act's enactment.

Document Availability

29. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

30. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

31. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202)502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

Effective Date and Congressional Notification

32. These regulations are effective April 5, 2019. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

2012), *http://www.sba.gov/sites/default/files/rfaguide_0512_0.pdf.*

[16] *Orengo Caraballo* v. *Reich,* 11 F.3d 186, 195 (D.C. Cir. 1993).

List of Subjects

18 CFR Part 4

Administrative practice and procedure, Electric power, Reporting and recordkeeping requirements.

18 CFR Part 11

Dams, Electric power, Indians-lands, Public lands, Reporting and recordkeeping requirements.

By the Commission.
Issued: February 22, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

In consideration of the foregoing, the Commission is amending parts 4 and 11, chapter I, title 18, *Code of Federal Regulations,* as follows:

PART 4—LICENSES, PERMITS, EXEMPTIONS, AND DETERMINATION OF PROJECT COSTS

■ 1. The authority citation for part 4 is revised to read:

Authority: 16 U.S.C. 791a–825r; 42 U.S.C. 7101–7352.

§ 4.30 [Amended]

■ 2. In § 4.30(b)(26)(ii), remove the number ''5'' and add in its place the number ''40''.

§ 4.81 [Amended]

■ 3. In § 4.81(a)(5), remove the number ''36'' and add in its place the number ''48''.

■ 4. In § 4.82, remove ''five'' and add in its place ''eight'' in paragraphs (a) and (c) and add paragraph (d) to read as follows:

§ 4.82 Amendments.

* * * * *

(d) At the end of the extension period granted under paragraph (a) of this section, the Commission may issue an additional permit to the permittee if the Commission determines that there are extraordinary circumstances that warrant the issuance of the additional permit.

§ 4.400 [Amended]

■ 5. In § 4.400, remove ''by the Hydropower Regulatory Efficiency Act of 2013''.

§ 4.401 [Amended]

■ 6. In § 4.401:

■ a. In paragraph (a)(3), remove ''the date of enactment of the Hydropower Regulatory Efficiency Act,''.

■ b. In paragraph (b), remove ''by section 4 of the Hydropower Regulatory Efficiency Act of 2013''.

PART 11—ANNUAL CHARGES UNDER PART I OF THE FEDERAL POWER ACT

■ 7. The authority citation for part 11 is revised to read:

Authority: 16 U.S.C. 791a–825r; 42 U.S.C. 7101–7352.

§ 11.1 [Amended]

■ 8. In § 11.1(c)(5), remove '', but in no case longer than four years after the issuance date of the license or exemption''.

[FR Doc. 2019–03742 Filed 3–5–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2015–F–2712]

Food Additives Permitted in Feed and Drinking Water of Animals; Selenomethionine Hydroxy Analogue

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 selenomethionine hydroxy analogue as a source of selenium in feed for chickens, turkeys, and swine, as well as to provide for the safe use of silicon dioxide as a carrier for selenomethionine hydroxy analogue. This action is in response to a food additive petition filed by Adisseo France S.A.S.

DATES: This rule is effective March 6, 2019. 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 April 5, 2019.

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 April 5, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 5, 2019. 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–2015–F–2712 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Selenomethionine Hydroxy Analogue.'' 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.gpo.gov/fdsys/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 Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–224), Rockville, MD 20855, 240–402–6729, *chelsea.trull@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In documents published in the **Federal Register** of August 13, 2015 (80 FR 48471), and October 30, 2018 (83 FR 54526), FDA announced that we had filed a food additive petition (animal use) (FAP 2291) submitted by Adisseo France S.A.S., Immeuble Antony Parc II, 10 Place du Général de Gaulle, 92160 Antony, France. 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 selenomethionine hydroxy analogue as a source of selenium in feed for chickens, turkeys, swine, dairy cattle, and beef cattle and the safe use of silicon dioxide as a carrier for selenomethionine hydroxy analogue at a level not to exceed 95 percent of the selenomethionine hydroxy analogue in its packaged form. Subsequently, the intended use of selenomethionine hydroxy analogue was limited to chickens, turkeys, and swine.

II. Conclusion

FDA concludes that the data establish the safety and utility of selenomethionine hydroxy analogue as a source of selenium in feed for chickens, turkeys, and swine, as well as silicon dioxide as a carrier for selenomethionine hydroxy analogue and that the food additive regulations should be amended as set forth in this document. This is not a significant regulatory action subject to Executive Order 12866.

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 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. Amend § 573.920 by:
■ a. Revising paragraph (b) and paragraph (c) introductory text,
■ b. Adding new paragraphs (c)(4) and (5);
■ c. Removing paragraph (d);
■ d. Redesignating paragraphs (e) through (h) as paragraphs (d) through (g);
■ e. Revising newly redesignated paragraph (g)(4); and
■ f. Adding new paragraph (h).

The revisions and additions read as follows:

§ 573.920 Selenium.

* * * * *

(b) The food additive selenium is a nutrient administered in animal feed as sodium selenite or sodium selenate as provided in paragraph (c) of this section, as a controlled-release sodium selenite bolus as provided in paragraph (f) of this section, as selenium yeast as provided in paragraph (g) of this section, or as selenomethionine hydroxy analogue as provided in paragraph (h) of this section.

(c) Selenium, as sodium selenite or sodium selenate, is added to feed as follows:

* * * * *

(4) The additive, as sodium selenite or sodium selenate, shall be incorporated into feed as follows:

(i) It shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(ii) It shall be incorporated into each ton of salt-mineral mixture for sheep or beef cattle from a premix containing no more than 4.5 grams of added selenium per pound.

(5) Usage of the additive must conform to the requirements of paragraphs (d) and (e) of this section.

* * * * *

(g) * * *

(4) Usage of this additive must conform to the requirements of paragraphs (d) and (e) of this section.

(h) Selenomethionine hydroxy analogue [R,S–2-hydroxy-4-methylselenobutanoic acid (CAS 873660–49–2)] is manufactured by the reaction of elemental selenium with methyllithium to form a methylseleno salt, which is then reacted with R,S–2-hydroxybutyrolactone to form a salt of 2-hydroxy-4-methylselenobutanoic acid. After acidification and purification, the additive consists of not less than 39.5 percent total selenium by weight with a selenomethionine hydroxy analogue content of not less than 98 percent of total selenium. The total organic selenium content of the additive is not less than 99 percent of total selenium.

(1) The selenomethionine hydroxy analogue meets the following specifications:

(i) Arsenic, not more than 2 parts per million (ppm);

(ii) Cadmium, not more than 1 ppm;

(iii) Lead, not more than 1 ppm; and

(iv) Mercury, not more than 1 ppm.

(2) Selenium, as selenomethionine hydroxy analogue, is added to complete feed for chickens, turkeys, and swine at a level not to exceed 0.3 ppm.

(3) 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 selenomethionine hydroxy analogue in its packaged form shall contain:

(i) The name, selenomethionine hydroxy analogue;

(ii) Minimum and maximum guarantees for a total selenium content of not less than 2.08 percent (weight/weight) and not more than 2.24 percent;

(iii) Minimum guarantee for selenomethionine hydroxy analogue content of not less than 5.2 percent;

(iv) The following statement, ''Storage Conditions: Selenomethionine hydroxy analogue must be stored in a closed package at temperatures not higher than 20 °C (68 °F).''; and

(v) An expiration date not to exceed 1 year from the date of manufacture.

(4) The additive, as selenomethionine hydroxy analogue, shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(5) Usage of this additive must conform to the requirements of paragraphs (d) and (e) of this section.

■ 3. Amend § 573.940 by adding an entry for ''Selenomethionine hydroxy analogue'' to the end of the table in paragraph (d) to read as follows:

§ 573.940 Silicon dioxide.

* * * * *

(d) * * *

Feed component	Limitations (percent)
* * * * *	
Selenomethionine hydroxy analogue	95

* * * * *

Dated: February 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03909 Filed 3–5–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2019–N–0138]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Software Application for Contraception

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the software application for contraception into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the software application for contraception's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective March 6, 2019. The classification was applicable on August 10, 2018.

FOR FURTHER INFORMATION CONTACT: Paige Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G627, Silver Spring, MD 20993–0002, 301–796–6417, *Paige.Brown@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: