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:

I. Background

Upon request, FDA has classified the software application for contraception as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on August 28, 2017, finding Natural Cycles not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On September 20, 2017, Natural Cycles Nordic AB submitted a request for De Novo classification of Natural Cycles. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on August 10, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 884.5370. We have named the generic type of device software application for contraception, and it is identified as a device that provides user-specific fertility information for preventing a pregnancy. This device includes an algorithm that performs analysis of patient-specific data (*e.g.,* temperature, menstrual cycle dates) to distinguish between fertile and non-fertile days, then provides patient-specific recommendations related to contraception.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—SOFTWARE APPLICATION FOR CONTRACEPTION RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Unintended pregnancy.	Software verification, validation, and hazard analysis; clinical performance testing; human factors and usability testing; and labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the

Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in part 820, regarding design controls, have been approved under OMB control number 0910–0073; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 884.5370 to subpart F to read as follows:

§ 884.5370 Software application for contraception.

(a) *Identification.* A software application for contraception is a device that provides user-specific fertility information for preventing a pregnancy. This device includes an algorithm that performs analysis of patient-specific data (*e.g.,* temperature, menstrual cycle dates) to distinguish between fertile and non-fertile days, then provides patient-specific recommendations related to contraception.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate the contraceptive effectiveness of the software in the intended use population.

(2) Human factors performance evaluation must be provided to demonstrate that the intended users can self-identify that they are in the intended use population and can correctly use the application, based solely on reading the directions for use for contraception.

(3) Software verification, validation, and hazard analysis must be performed. Documentation must include the following:

(i) A cybersecurity vulnerability and management process to assure software functionality; and

(ii) A description of the technical parameters of the software, including the algorithm used to determine fertility status and alerts for user inputs outside of expected ranges.

(4) Labeling must include:

(i) The following warnings and precautions:

(A) A statement that no contraceptive method is 100% effective.

(B) A statement that another form of contraception (or abstinence) must be used on days specified by the application.

(C) Statements of any factors that may affect the accuracy of the contraceptive information.

(D) A warning that the application cannot protect against sexually transmitted infections.

(ii) Hardware platform and operating system requirements.

(iii) Instructions identifying and explaining how to use the software application, including required user inputs and how to interpret the application outputs.

(iv) A summary of the clinical validation study and results, including effectiveness of the application as a stand-alone contraceptive and how this effectiveness compares to other forms of legally marketed contraceptives.

Dated: February 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04028 Filed 3–5–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0126]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, Port Gibson, MS

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing an emergency temporary safety zone for all navigable waters of the Lower Mississippi River, extending the entire width of the river, from mile marker (MM) 405 to MM 408. This emergency safety zone is necessary to protect persons, property, and infrastructure from potential damage and safety hazards associated with vessels transiting this area during high water. This rule prohibits persons and vessels from entering the safety zone area unless specifically authorized by the Captain of the Port Sector Lower Mississippi River (COTP) or a designated representative.

DATES: This rule is effective without actual notice from March 6, 2019 through 7 p.m. on April 15, 2019, or until the high water event ceases, whichever occurs first. For the purposes of enforcement, actual notice will be used from February 28, 2019 through March 6, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2019–0126 in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Open Docket Folder'' on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Todd Manow, Sector Lower Mississippi River Prevention Department, U.S. Coast Guard; telephone 901–521–4813, email *Todd.M.Manow@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Lower Mississippi River
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. Increasing high water in