(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on August 21, 2024.

Suzanne Masterson,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2024–20111 Filed 9–3–24; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2024–F–3882]

Food Additives Permitted in Feed and Drinking Water of Animals; Pichia Pastoris Dried Yeast

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to update the organism *Pichia pastoris* which has been renamed as *Komagataella pastoris.* Additionally, the food additive regulation is being updated to include language to clarify that the yeast is non-viable in the market formulation. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective September 5, 2024.

FOR FURTHER INFORMATION CONTACT: Chelsea Cerrito, Center for Veterinary Medicine, Division of Animal Food Ingredients, Food and Drug Administration, 12225 Wilkins Ave., Rockville, MD 20852, 240–402–6729, *Chelsea.Cerrito@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the food additive regulation at 21 CFR 573.750 Pichia pastoris dried yeast for use in animal feed to update the organism *Pichia pastoris* which has been renamed as *Komagataella pastoris.* Additionally, the food additive regulation is being updated to include language to clarify that the yeast is non-viable in the market formulation. This action is being taken to improve the accuracy of the regulations.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes including updating scientific nomenclature and is nonsubstantive.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, and under the 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.

§ 573.750 [Redesignated as § 573.587]

■ 2. Redesignate § 573.750 as § 573.587.

■ 3. Amend newly redesignated § 573.587 by revising the section heading and paragraph (a) to read as follows:

§ 573.587 Komagataella pastoris dried yeast.

(a) *Identity.* The food additive *Komagataella pastoris* dried yeast is non-viable and may be used in feed formulations of broiler chickens as a source of protein not to exceed 10 percent by weight of the total formulation.

* * * * *

Dated: August 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19856 Filed 9–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA–2024–N–3971]

Medical Devices; Hematology and Pathology Devices; Classification of the Heparin and Direct Oral Factor Xa Inhibitor Drug Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the heparin and direct oral factor Xa inhibitor drug test system 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 heparin and direct oral factor Xa inhibitor drug test system'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.

DATES: This order is effective September 5, 2024. The classification was applicable on September 17, 2020.

FOR FURTHER INFORMATION CONTACT: Min Wu, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3459, Silver Spring, MD 20993–0002, 301–348–1886, *Min.Wu@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the heparin and direct oral factor Xa inhibitor drug test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

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 (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device 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 (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. 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 is required to 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 placed within class III, the De Novo classification is considered to be the initial classification of the device.

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 section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 25, 2019, FDA received Instrumentation Laboratory Co.'s request for De Novo classification of the HemosIL Liquid Anti-Xa. 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 September 17, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 864.7295.[1] We have named the generic type of device heparin and direct oral factor Xa inhibitor drug test system, and it is identified as a drug test system intended for the detection of heparin and direct oral factor Xa inhibitors in human specimens collected from patients taking heparin or direct oral factor Xa inhibitors. The device is intended to aid in the management of therapy in conjunction with other clinical and laboratory findings.

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—HEPARIN AND DIRECT ORAL FACTOR Xa INHIBITOR DRUG TEST SYSTEM; RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
False positive/false negative/failed to provide a result for diagnostics	Certain analytical studies and clinical studies in design verification and validation, and Certain labeling information.

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. 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. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR 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; the

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for part 864 continues to read as follows:

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

■ 2. Add § 864.7295 to subpart H to read as follows:

§ 864.7295 Heparin and direct oral factor Xa inhibitor drug test system.

(a) *Identification.* A heparin and direct oral factor Xa inhibitor drug test system is intended for the detection of heparin and direct oral factor Xa inhibitors in human specimens collected from patients taking heparin or direct oral factor Xa inhibitors. This device is intended to aid in the management of therapy in conjunction with other clinical and laboratory findings.

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

(1) Design verification and validation must include the following:

(i) Detailed documentation of analytical device performance studies and results demonstrating acceptable analytical performance with a sufficient number of specimens tested in order to obtain unbiased estimates of analytical performance. This documentation shall include the following as appropriate to the technology, specimen types tested, and intended use of the device:

(A) Studies and results for that demonstrate device precision including repeatability and reproducibility, using quality controls and clinical samples, when appropriate. Precision studies must assess specimens for each indicated drug at concentrations throughout the measuring range of the device including near clinically relevant levels, as appropriate. The study must evaluate different sources of variability including, as appropriate, between-run, between-operator, between-lot, between-instrument, between-day, and between-site;

(B) Studies and results that demonstrate that the device is free from clinically significant interference, from endogenous and exogenous interferents associated with the target population(s), and interferents that are specific for, or related to, the technology or methodology of the device;

(C) Data to demonstrate appropriate specimen stability for the intended sample matrices under the intended conditions for specimen collection, handling, and storage described in the device labeling;

(D) Studies and results that demonstrate the linear range, limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ), as applicable to the technology of the device; and

(E) For any devices intended for use for near patient testing, studies and results that demonstrate the robustness of the device in the hands of the intended user, including the entire testing procedure, pre-analytical specimen processing steps, and results interpretation.

(ii) Detailed documentation of clinical performance testing in which the performance is analyzed relative to a comparator that FDA has determined is appropriate. Specimens must be representative of the intended use population(s) and must cover the full range of the device output and any clinically relevant decision points as appropriate.

(2) The labeling required under § 809.10(b) of this chapter must include:

(i) Identification of any known interferents, including all endogenous, exogenous, technology-specific, and patient population-specific interferents, specific to the test outputs. The information must include the concentration(s) or level(s) of the interferent at which clinically significant interference was found to occur, and the concentration range or levels at which interference was not found to occur;

(ii) A prominent statement that the device is not intended for use in monitoring patients taking heparin or direct oral factor Xa inhibitors; and

(iii) Limiting statements indicating, as applicable:

(A) That the device should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures; and

(B) That the device is not specific to the direct oral factor Xa inhibitor that has been evaluated and may detect the presence of other direct factor Xa inhibitors that have not been evaluated.

Dated: August 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19824 Filed 9–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2024–N–3947]

Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Open Loop Fluid Therapy Recommender

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the adjunctive open loop fluid therapy recommender 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 adjunctive open loop fluid therapy recommender'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.

DATES: This order is effective September 5, 2024. The classification was applicable on November 13, 2020.

FOR FURTHER INFORMATION CONTACT: Biniyam Taddese, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2544, Silver Spring, MD 20993–0002, 240–402–6570, *Biniyam.Taddese@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the adjunctive open loop fluid therapy recommender as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

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