(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