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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, and 524

[Docket No. FDA–2025–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Application; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (CNADAs) during January, February, and March 2025. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective May 9, 2025.

FOR FURTHER INFORMATION CONTACT: Barbara Leotta, DVM, Deputy Office Director, Office of New Animal Product Evaluation Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0605, *Barbara.Leotta@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval of New Animal Drug Applications

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January, February, and March 2025, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOIA Summaries) under the Freedom of Information Act (FOIA). These documents, along with marketing exclusivity and patent information, may be obtained at Animal Drugs @FDA: *https://animaldrugsatfda.fda.gov/adafda/views/#/search.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2025 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Date of approval	File No.	Sponsor (drug labeler code [1])	Product name	Effect of the action	21 CFR section
January 13, 2025	200–626	Bimeda Animal Health Ltd. (061133).	EPRIMECTIN Pour-On (eprinomectin).	Original approval as a generic copy of NADA 141–079.	524.814
February 25, 2025	200–742	Hikma Pharmaceuticals USA, Inc. (086194.	Tulathromycin Injection (tulathromycin injection) Injectable Solution.	Original approval as a generic copy of NADA 141-244.	522.2630

[1] See 21 CFR 510.600(c) for sponsor addresses.

II. Withdrawal of Approval of New Animal Drug Applications

Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096 (drug labeler code 000010) requested that FDA withdraw approval of ANADA 200–088 for SEDAZINE (xylazine hydrochloride) Injectable Solution because the product is no longer manufactured or marketed. Accordingly, approval of ANADA 200–088 was withdrawn effective December 10, 2023. The animal drug regulations are being amended to reflect this action.

III. Changes of Sponsor

The sponsors of the approved applications listed in table 3 have informed FDA that they have transferred ownership of, and all rights and interest in, these applications to another sponsor. The regulations cited in table 2 are amended to reflect these actions.

TABLE 2—APPLICATIONS FOR WHICH OWNERSHIP WAS TRANSFERRED TO ANOTHER SPONSOR DURING JANUARY, FEBRUARY, AND MARCH 2025

File No.	Product name	Transferring sponsor (drug labeler code)	New sponsor (drug labeler code)	21 CFR section
200–379	VETPROFEN (carprofen) Caplets	Belcher Pharmaceuticals, Inc. (051233).	Ajenat Pharmaceuticals, LLC (082983).	520.304
200–578	Carprofen Flavored Tablets (carprofen).	Do	Do	520.304

IV. Technical Amendments

FDA is making the following amendments to improve the accuracy and readability of the animal drug regulations.

- 21 CFR 510.600(c) is amended to remove entries for Belcher Pharmaceuticals, LLC, as the firm is no longer the sponsor of approved applications, and to add entries for Ajenat Pharmaceuticals, LLC and Hikma Pharmaceuticals USA, Inc.
- 21 CFR 522.772 is amended to present an accurate list of bovine parasites.
- 21 CFR 522.2005 is amended to introduce sponsor drug labeler codes for approved propofol injectable solution.
- 21 CFR 522.2630(c) is amended to present the sequence of drug labeler codes for tulathromycin injectable solutions.

V. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)). Although deemed a rule pursuant to the FD&C Act, this document does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a ''rule of particular applicability'' and is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 516, 520, 522, and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600:

■ a. In the table in paragraph (c)(1):

■ i. Remove the entry for ''Belcher Pharmaceuticals, LLC'';

■ ii. Add an entry for ''Ajenat Pharmaceuticals, LLC''; and

■ iii. Add an entry for ''Hikma Pharmaceuticals USA, Inc.''; and

■ b. In the table in paragraph (c)(2):

■ i Remove the entry for ''062250''; and

■ ii Add entries for ''082983'' and ''086194''.

The additions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Ajenat Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Suite 210, Largo, FL 33777	082983
* * * * * * *	
Hikma Pharmaceuticals USA, Inc., 2 Esterbrook Ln., Cherry Hill, NJ 08003	086194
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
082983	Ajenat Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Suite 210, Largo, FL 33777
* * * * * * *	
086194	Hikma Pharmaceuticals USA, Inc., 2 Esterbrook Ln., Cherry Hill, NJ 08003
* * * * * * *	

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 4. Add § 516.2106 to subpart E to read as follows:

§ 516.2106 Sirolimus.

(a) *Specifications.* Each sustained-release tablet contains 0.4, 1.2, or 2.4 milligrams (mg) sirolimus.

(b) *Sponsor.* See No. 086169 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer orally once weekly at a dose of 0.3 mg/kilogram of bodyweight.

(2) *Indications for use.* For the management of ventricular hypertrophy in cats with subclinical hypertrophic cardiomyopathy (HCM).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 5. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.304 [Amended]

■ 6. In § 520.304, in paragraph (b)(1), remove the text ''062250'' and in its place add the text ''082983''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 7. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.772 [Amended]

■ 8. In § 522.772, in paragraph (d)(1)(ii), remove the text ''*Oncophora, Cooperia pectinata* (adults only)'' and in its place add the text ''*Cooperia oncophora, C. pectinata* (adults only)''

■ 9. In § 522.2005, revise paragraph (b) introductory text to read as follows:

§ 522.2005 Propofol.

* * * * *

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

* * * * *

§ 522.2662 [Amended]

■ 10. In § 522.2662, in paragraph (b)(2), remove the text ''Nos. 000010 and 061133'' and in its place add the text ''No. 061133''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 11. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.814 [Amended]

■ 12. In § 524.814, in paragraph (b), remove the text ''and 055529'' and in its place add the text ''055529, and 061133''.

Dated: May 5, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08137 Filed 5–8–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2025–N–0780]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Voriconazole Test System

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the voriconazole 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 voriconazole 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, in part by reducing regulatory burdens.

DATES: This order is effective May 9, 2025. The classification was applicable on May 5, 2017.

FOR FURTHER INFORMATION CONTACT: Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 301–796–2411, *Dina.Jerebitski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the voriconazole test system 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 (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.

We believe this De Novo classification will enhance patients' access to