Avilamycin in grams/ton	Indications for use	Limitations	Sponsor
*	*	* * * * *	
(ii) 13.6 to 40.9	Monensin, 90 to 110	Feed as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens* in broiler chickens. Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. Do not feed to chickens over 16 weeks of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. Do not allow horses or other equines access to feed containing avilamycin and monensin. Ingestion of monensin by horses has been fatal. Do not feed to chickens producing eggs for human consumption. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	058198
(iii) 13.6 to 40.9	Narasin, 54 to 90	Feed as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens.* Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Do not feed to chickens producing eggs for human consumption. Narasin as provided by No. 058198 in § 510.600(c) of this chapter.	058198
*	*	* * * * *	
(v) 13.6 to 40.9	Salinomycin sodium, 40 to 60	Feed as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens.* Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. May be fatal if fed to adult turkeys or to horses. Not approved for use with pellet binders. Do not feed to laying hens producing eggs for human consumption. Salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.	058198

* * * * *

■ 28. In § 558.355, revise paragraphs (b) and (f)(6)(i) to read as follows:

§ 558.355 Monensin.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (f) of this section.

(1) No. 058198 for use as in paragraph (f) of this section.

(2) No. 016592 for use of a Type A medicated article containing 90.7 grams monensin, USP, per pound as in paragraphs (f)(3), (f)(4)(vi), and (f)(6) of this section.

* * * * *

(f) * * *

(6) * * *

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 20	For the prevention of coccidiosis caused by *Eimeria crandallis, E. christenseni,* and *E. ninakohlyakimovae.*	Feed only to goats being fed in confinement. Do not feed to lactating goats. See paragraph (d)(11) of this section for provisions for monensin liquid Type C goat feeds.	058198
*	*	* * * * *	

* * * * *

§ 558.625 [Amended]

■ 29. Amend § 558.625:

■ a. By removing ''monensin as provided by No. 058198'' and adding in its place ''monensin as provided by Nos. 016592 or 058198'' in the ''Limitations'' column, in:

■ 1. Paragraph (e)(2)(iv),

■ 2. Paragraph (e)(2)(v),

■ 3. Paragraph (e)(2)(x),

■ 4. Paragraph (e)(2)(xi),

■ 5. Paragraph (e)(2)(xii), and

■ 6. Paragraph (e)(2)(xiii); and

■ b. By adding ''016592'' in numerical order in the ''Sponsors'' column in:

■ 1. Paragraph (e)(2)(x),

■ 2. Paragraph (e)(2)(xi),

■ 3. Paragraph (e)(2)(xii), and

■ 4. Paragraph (e)(2)(xiii).

Dated: January 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00421 Filed 1–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 529

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Withdrawal of Approval of a New Animal Drug Application; Withdrawal of Approval of Abbreviated New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) and two abbreviated new animal drug applications (ANADAs) at the sponsors' request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is applicable February 3, 2020.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234, has requested that FDA withdraw approval of NADA 010–005 for use of WAZINE (dipiperazine sulfate and piperazine hydrochloride) Soluble Powders because the product is no longer manufactured or marketed.

Also, Halocarbon Products Corp., 6525 The Corners Pkwy., Suite 200, Peachtree Corners, GA 30092, has requested that FDA withdraw approval of ANADA 200–200 for use of Halothane USP (halothane) because the product is no longer manufactured or marketed.

Lastly, Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103, has requested that FDA withdraw approval of ANADA 200–472 for use of Fomepizole Injection because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 010–005 and ANADAs 200–200 and 200–472, and all supplements and amendments thereto, is hereby withdrawn, effective February 3, 2020.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: January 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00422 Filed 1–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–446]

Schedules of Controlled Substances: Placement of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA.

DATES: Effective: January 24, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated on the Attorney General's own motion, as delegated to the Administrator of the DEA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of HHS and an evaluation of all relevant data by the DEA. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA.

Background

On April 10, 2017, DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place the six synthetic cannabinoids (SCs) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA] in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 82 FR 17119. That temporary scheduling order was effective on the date of publication, and was based on findings by the former Acting Administrator of the DEA (Acting Administrator) that the temporary scheduling of these six SCs was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of

[1] As set forth in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the Department of Health and Human Services (HHS) in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.