Dated: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21146 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, 524, and 558

[Docket No. FDA–2018–N–0002]

New Animal Drugs; Withdrawal of Approval of 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 12 new animal drug applications (NADAs) at the sponsor's request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective October 9, 2018.

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: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, has requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Product name	21 CFR section
011–779 ...	PURINA PIGEMIA 100 (colloidal ferric oxide).	522.1182
040–205 ...	PURINA Horse Wormer Medicated (thiabendazole).	520.2380a
042–116 ...	PURINA 6 DAY WORM-KILL Feed Premix (coumaphos).	558.185
043–215 ...	PURINA GRUB-KILL Pour-on Cattle Insecticide (famphur).	524.900
046–700 ...	STATYL Medicated Premix (nequinate).	558.365
091–260 ...	PULVEX WORM CAPS (piperazine phosphate monohydrate).	520.1804
097–258 ...	PURINA BAN-WORM for Pigs (pyrantel tartrate).	558.485
102–942 ...	PULVEX Multipurpose Worm Caps (dichlorophene, toluene).	520.580
113–748 ...	PURINA PIGEMIA Oral (iron dextran complex).	520.1182
135–941 ...	CHECK-R-TON BM (pyrantel tartrate).	558.485
136–116 ...	PURINA WORM-A-REST™ Litter Pack Premix (fenbendazole).	520.905d
140–869 ...	PURINA SAF-T-BLOC BG Medicated Feed Block (poloxalene, 6.6%).	520.1840

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 NADAs 011–779, 040–205, 042–116, 043–215, 046–700, 091–260, 097–258, 102–942, 113–748, 135–941, 136–116, and 140–869, and all supplements and amendments thereto, is hereby withdrawn, effective October 9, 2018.

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: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21147 Filed 9–27–18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1308, 1312

[Docket No. DEA–486]

Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: With the issuance of this final order, the Acting Administrator of the Drug Enforcement Administration places certain drug products that have been approved by the Food and Drug Administration (FDA) and which contain cannabidiol (CBD) in schedule V of the Controlled Substances Act (CSA). Specifically, this order places FDA-approved drugs that contain CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V. This action is required to satisfy the responsibility of the Acting Administrator under the CSA to place a drug in the schedule he deems most appropriate to carry out United States obligations under the Single Convention on Narcotic Drugs, 1961. Also consistent therewith, DEA is adding such drugs to the list of substances that may only be imported or exported pursuant to a permit.

DATES: Effective September 28, 2018.

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

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The United States is a party to the Single Convention on Narcotic Drugs, 1961 (Single Convention), and other international conventions designed to establish effective control over international and domestic traffic in controlled substances. 21 U.S.C. 801(7). The Single Convention entered into force for the United States on June 24, 1967, after the Senate gave its advice and consent to the United States' accession. *See* Single Convention, 18 U.S.T. 1407. The enactment and enforcement of the Controlled Substances Act (CSA) are the primary means by which the United States carries out its obligations under the Single Convention.[1] Various provisions of the CSA directly reference the Single Convention. One such provision is 21 U.S.C. 811(d)(1), which relates to scheduling of controlled substances.

As stated in subsection 811(d)(1), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by [subsections 811(a) or 812(b)] and without regard to the procedures prescribed by [subsections 811(a) and (b)].'' This provision is consistent with the Supremacy Clause of the U.S. Constitution (art. VI, sec. 2), which provides that all treaties made under the authority of the United States ''shall be the supreme Law of the Land.'' In accordance with this constitutional

[1] *See* S. Rep. No. 91–613, at 4 (1969) (''The United States has international commitments to help control the worldwide drug traffic. To honor those commitments, principally those established by the Single Convention on Narcotic Drugs of 1961, is clearly a Federal responsibility.''); *Control of Papaver Bracteatum,* 1 Op. O.L.C. 93, 95 (1977) (''[A] number of the provisions of [the CSA] reflect Congress' intent to comply with the obligations imposed by the Single Convention.'').