4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 526

[Docket No. FDA-2019-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 eight new animal drug applications (NADAs) at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE OF FILING FOR PUBLIC INSPECTION AT THE *FEDERAL REGISTER*].

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: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, 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
055-036	PRINCILLIN (ampicillin trihydrate) Capsules	520.90c
055-050	PRINCILLIN (ampicillin trihydrate) Soluble Powder	520.90e
055-056	PRINCILLIN (ampicillin trihydrate) Bolus	520.90f
055-061	PRINCILLIN "125" For Oral Suspension	520.90d
055-068	BOVICLOX (cloxacillin benzathine)	526.464b
065-013	Dihydrostreptomycin (dihydrostreptomycin sulfate)	522.650

065-493	JETPEN (penicillin G benzathine and penicillin G procaine) Aqueous Suspension	522.1696a
065-500	TANDEM PEN (penicillin G procaine)	522.1696b

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 055-036, 055-050, 055-056, 055-061, 055-068, 065-013, 065-493, and 065-500, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE OF FILING FOR PUBLIC INSPECTION AT THE *FEDERAL REGISTER*].

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: March 25, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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