



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2017-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 three new animal drug applications (NADAs). This action is being taken at the sponsors' request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN 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](mailto:sujaya.dessai@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: During July and August 2017, the following sponsors requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product Name	21 CFR Section
047-055	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880	Chorionic Gonadotropin Powder for Injection	522.1081
104-606	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880	Dexamethasone Sodium Phosphate Injection	522.540
139-633	Wildlife Laboratories, Inc., 1230 W. Ash St., suite D, Windsor, CO 80550	WILDNIL (carfentanil citrate) Injection	522.300

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is given that approval of NADAs 047-055, 104-606, and 139-633, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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