4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Quali-Tech Products, Inc.; Bambermycins; Pyrantel; Tylosin; Virginiamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADAs) held by Quali-Tech Products, Inc., at the sponsor's request because the 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: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; 240-453-6843; email: david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Quali-Tech Products, Inc., has requested that FDA withdraw approval of the following four NADAs because the products, used to manufacture Type C medicated feeds, are no longer manufactured or marketed: NADA 097-980 for Quali-Tech TYLAN-10 (tylosin phosphate) Premix, NADA 118-815 for Q.T. BAN-TECH (pyrantel tartrate), NADA 132-705 for FLAVOMYCIN (bambermycins), and NADA 133-335 for STAFAC (virginiamycin) Swine Pak 10.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADAs 097-980, 118-815, 132-705, and 133-335, and all supplements and amendments thereto, is hereby withdrawn.

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: August 20, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2013-20615 Filed 08/22/2013 at 8:45 am; Publication Date: 08/23/2013]