

for public review in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-24213 Filed 10-2-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0981]

Withdrawal of Approval of New Animal Drug Applications; Butorphanol; Doxapram; Triamcinolone; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) and three abbreviated new animal drug

applications (ANADAs) at the sponsors' request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective October 15, 2012.

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: The following sponsors have requested that FDA withdraw approval of the NADA and ANADAs listed in table 1 of this document because the products are no longer manufactured or marketed.

TABLE 1—NADA AND ANADAs FOR WHICH WITHDRAWAL OF APPROVAL HAS BEEN REQUESTED

NADA/ANADA No.	Trade name (drug)	Applicant
100-556	Vigorena Feeds Hy-Ty Premix (tylosin phosphate)	Springfield Milling Corp., Vigorena Feeds, Springfield, MN 56087.
200-435	RESPIRAM (doxapram hydrochloride) Injection	Modern Veterinary Therapeutics, LLC, 18001 Old Cutler Rd., Suite 317, Miami, FL 33157.
200-446	BUTORPHINE (butorphanol tartrate) Injection	Modern Veterinary Therapeutics, LLC, 18001 Old Cutler Rd., Suite 317, Miami, FL 33157.
200-459	VETAZINE (triamcinolone) Cream	Modern Veterinary Therapeutics, LLC, 18001 Old Cutler Rd., Suite 317, Miami, FL 33157.

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of NADA 100-556 and ANADAs 200-435, 200-446, and 200-459, and all supplements and amendments thereto, is hereby withdrawn, effective October 15, 2012.

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 27, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012-24330 Filed 10-2-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT:

Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A Novel Immortalized Human Adrenal Cell Line With Inactive Protein Kinase A for Studies on cAMP Signaling and Endocrine Tumorigenesis

Description of Technology: The first known immortalized cell line with a naturally-occurring inactivating mutation in PRKAR1A, the regulatory subunit type 1A (R1alpha) of protein

kinase A (PKA), which is associated with tumor formation.

PKA isozyme balance is critical for the control of cAMP signaling and related cell cycle and proliferation changes. Aberrant cAMP signaling has been linked to adrenocortical and other, mostly endocrine, tumors. Inactivating mutations in the PRKAR1A gene are a known cause of Carney Complex—an autosomal dominant multiple neoplasia syndrome associated with skin, heart, and other myxomas and a variety of endocrine tumors.

Potential Commercial Applications:

- Studies on multiple tumor formation associated with Carney Complex.
- Characterization of cAMP-mediated mechanisms of endocrine tumor formation.
- Studies of a large variety of cAMP-mediated processes in normal physiology and disease.

Competitive Advantages: First known immortalized cell line with a naturally-occurring inactivating mutation in the PRKAR1A gene.

Development Stage: In vitro data available.

Inventor: Constantine A. Stratakis (NICHD).

Publication: Nesterova M, *et al.* An immortalized human cell line bearing a PRKAR1A-inactivating mutation: effects of overexpression of the wild-type