

45 minutes. The course will be presented mainly by senior FDA staff, with guest lecturers presenting selected topics.

The course will address FDA's role in clinical studies, regulatory considerations for clinical trials, and review of the material generally appearing in an "investigator's brochure," i.e., the preclinical information (toxicology, animal studies, and chemistry/manufacturing information) that supports initial clinical trials in humans. Presenters will discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. The course will also include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. On November 15, 2012, participants will choose among three breakout sessions that will explain how to put together an application to FDA for drugs, biologics, or devices.

#### C. Target Audience

The course is targeted at health care professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Dated: September 26, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-24214 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-0284]

#### Pediatric Studies of Sodium Nitroprusside Conducted in Accordance With Section 409I of the Public Health Service Act; Establishment of Public Docket

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the opening of a public docket to make available to the public a report of the pediatric studies of sodium nitroprusside that were conducted in accordance with the Public Health Service Act (the PHS Act) and submitted to the Director of the National Institutes of Health (NIH) and the Commissioner of Food and Drugs.

**DATES:** Submit either electronic or written comments by November 2, 2012.

**ADDRESSES:** You may submit comments, identified by FDA-2012-N-0284, by any of the following methods.

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and Docket No. for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Akilah Green, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6475, Silver Spring, MD 20993-0002, email: [akilah.green@fda.hhs.gov](mailto:akilah.green@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under section 409I of the PHS Act (42 U.S.C. 284m), the Secretary of the Department of Health and Human Services (the Secretary) acting through the Director of NIH, in consultation with FDA and experts in pediatric research, must develop, prioritize, and publish a list of priority needs in pediatric therapeutics, including drugs, biological products, and indications that require study.<sup>1</sup> For drugs and biological products and indications on this list, FDA, acting in consultation with NIH, is authorized to issue a written request to holders of a new drug application (NDA) or abbreviated new drug application (ANDA) for a drug, or holders of a biologics license application (BLA) for a

biological product, for which pediatric studies are needed to provide safety and efficacy information for pediatric labeling. If the sponsors receiving the written request decline to conduct the studies or if FDA does not receive a response to the written request within 30 days of the date the written request was issued, the Secretary, acting through the Director of NIH and in consultation with FDA, must publish a request for proposals to conduct the pediatric studies described in the written request and award funds to an entity with appropriate expertise for the conduct of the pediatric studies described in the written request. Upon completion of the pediatric studies, a study report that includes all data generated in connection with the studies must be submitted to FDA and NIH and placed in a public docket assigned by FDA.

Sodium nitroprusside, a hypotensive agent, is labeled for the immediate reduction of blood pressure of patients in hypertensive crises, for producing controlled hypotension in order to reduce bleeding during surgery, and for the treatment of acute congestive heart failure. Off-label use of sodium nitroprusside in pediatric patients is significant, despite the lack of adequate pharmacokinetic, dosing, tolerability, and safety data for this age group.

On January 21, 2003, NIH published a **Federal Register** notice (68 FR 2789) announcing the addition of several drugs, including sodium nitroprusside, to the priority list of drugs most in need of study for use by children to ensure their safety and efficacy. A written request for pediatric studies of sodium nitroprusside was issued on July 8, 2002, to Abbott Laboratories, the holder of the NDA for sodium nitroprusside. FDA did not receive a response to the written request. Accordingly, NIH issued a request for proposals to conduct the pediatric studies described in the written request in July 2004, and awarded funds to Duke University and Stanford University in September 2004, to complete the studies described in the written request. Upon completion of the pediatric studies, a report of the pediatric studies of sodium nitroprusside was submitted to NIH and FDA. As required under section 409I of the PHS act, FDA opened a public docket and NIH placed in the docket the report of pediatric studies of sodium nitroprusside that was submitted to NIH and FDA. The report includes all data generated in connection with the study, including the written request.

We invite interested parties to review the report and submit comments to the docket. The public docket is available

<sup>1</sup> Prior to the 2007 reauthorization of the Best Pharmaceuticals for Children Act (Pub. L. 107-109), the priority list included specific drugs instead of therapeutic areas.

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](mailto: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]

**BILLING CODE 4160-01-P**

## 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