**FOR FURTHER INFORMATION CONTACT:** Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment." This draft guidance addresses nonclinical development, early phases of clinical development, phase 3 protocol designs, and endpoints for the treatment of CHC, including in patients who are treatment naïve or experienced, patients without cirrhosis, patients with compensated and decompensated cirrhosis, and patients co-infected with HCV and HIV. Important issues addressed in this guidance include: Drug development methods to reduce the emergence of drug resistance, types of trial designs to assess optimal dose and treatment duration, combination therapy with multiple investigational drugs, recommendations on development of drugs to meet unmet medical needs, and use of treatment INDs or other smaller safety protocols to provide early access of multiple DAAs for patients at risk of imminent progression of liver disease.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing DAAs for treatment of CHC virus infection. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001, and the collections of information referred to in the guidance "Establishment and Operation of Clinical Trial Data Monitoring Committees" have been approved under OMB control number 0910–0581.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: September 8, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–22806 Filed 9–13–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0455]**

### North American Bioproducts Corporation; Filing of Food Additive Petition (Animal Use); Penicillin G Procaine

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that North American Bioproducts Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of penicillin G procaine as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its consequent presence in by-product distiller grains used as an animal feed or feed ingredient.

**DATES:** Submit either electronic or written comments on the petitioner's environmental assessment by October 14, 2010.

**ADDRESSES:** Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853, email: *isabel.pocurull@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2268) has been filed by North American Bioproducts Corp., Corporate Support Center, 1815 Satellite Blvd., Bldg. 200, Duluth, GA 30097. The petition proposes to amend the food additive regulations in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of penicillin G procaine as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its consequent presence in by-product distiller grains used as an animal feed or feed ingredient.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **ADDRESSES**) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. It is only necessary to submit one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: September 8, 2010.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2010–22811 Filed 9–13–10; 8:45 am]

**BILLING CODE 4160–01–S**

## 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.

**ADDRESSES:** 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.

**Assay for Arf GTP-Binding Proteins**

*Description of Invention:* The worldwide laboratory research reagents market is expected to surpass $13 billion in 2010, and the field of biotechnology appears key to maintaining the market's growth. Antibodies are becoming increasingly significant, especially for targeting the diseased cells and cell compounds.

Researchers at the National Cancer Institute (NCI), NIH, have developed an antibody-based assay that measures levels of Arf GTP-binding proteins, some of which have been linked to the invasive behavior of cancer cells. The assay is robust, can be performed both on cell lysates and fixed cells, and can distinguish among specific endogenous Arf-GTP isoforms.

*Applications:*

• Research on Arf function in physiology and cancer.

• Research on cancer invasion.

• Research on membrane traffic and actin reorganization.

*Advantages:*

• Ability to distinguish between the specific isoforms (i.e., Arf1, Arf3, Arf4, Arf5, and Arf6).

• Antibodies bind preferentially to the GTP-bound form of Arf.

*Inventor:* Paul A. Randazzo (NCI).

*Relevant Publications:*

1. Spang A *et al.* Arf GAPs: gatekeepers of vesicle generation. FEBS Lett. 2010 Jun 18;584(12):2646–2651. [PubMed: 20394747].

2. Campa F and Randazzo PA. Arf GTPase-activating proteins and their potential role in cell migration and invasion. Cell Adh Migr. 2008 Oct; 2(4):258–262. [PubMed: 19262159].

*Patent Status:* HHS Reference No. E–198–2010/0—Research Material. Patent protection is not being pursued for this technology.

*Licensing Status:* Available for licensing.

*Licensing Contact:* Patrick P. McCue, PhD, (301) 435–5560; *mccuepat@mail.nih.gov*.

*Collaborative Research Opportunity:* The Center for Cancer Research, Laboratory of Cellular and Molecular Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

**Sequences Encoding Two Novel Human Polyomaviruses**

*Description of Invention:* Researchers at the National Cancer Institute, NIH, have discovered two species of a previously unknown polyomavirus genus.

Polyomaviruses are a diverse group of DNA-based viruses that infect humans and various animals. At least one human polyomavirus, the Merkel cell polyomavirus (MCV), plays a causal role in the development of an unusual form of skin cancer called Merkel cell carcinoma. The coat proteins of polyomaviruses can spontaneously assemble into virus-like particles (VLPs) similar to those that have been used in the recent vaccines against human papillomaviruses (HPVs).

*Applications:*

• Development of clinical diagnostic assays to detect linkages between the new polyomaviruses and human cancers.

• Development of a VLP-based prophylactic vaccine similar to the HPV vaccine.

*Advantages:* DNA sequences have broad applications in the studies of polyomavirus infection mechanisms and carcinogenesis. Notably, they are:

• Identification and purification of the normal and mutated polyomaviral proteins.

• Studies of antisense oligonucleotides in polyomavirus biology.

• Development of polyclonal and monoclonal antibodies against polyomaviruses.

*Development Status:* Pre-clinical.

*Inventors:* Christopher B. Buck and Diana V. Pastrana (NCI).

*Relevant Publication:* Schowalter RM *et al.* Merkel cell polyomavirus and two previously unknown polyomaviruses are chronically shed from human skin. Cell Host Microbe Jun 25;7(6):509–515. [PubMed: 20542254].

*Patent Status:* U.S. Provisional Application No. 61/318,080 filed 26 Mar 2010 (HHS Reference No. E–051–2010/0–US–01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Patrick P. McCue, PhD; 301–435–5560; *mccuepat@mail.nih.gov*.

**Fenoterol and Fenoterol Analogues for Treatment of Glioma, Glioblastoma, and Astrocytoma**

*Description of Invention:* To date there is no effective treatment for the brain tumors or brain cancers indentified as gliomas, glioblastomas, or astrocytomas.

This technology relates to the discovery that fenoterol and related analogues block astrocytoma and glioblastoma cell division at low doses. In a xenograft model utilizing the 1321N1 astrocytoma tumor implanted in the flank of SKID mice, the (R,R)-4-methoxyfenoterol analogue significantly decreased tumor growth relative to a control group receiving vehicle and studies utilizing [$^3$H]-(R,R)-4-methoxyfenoterol have shown that the compound readily passes the blood-brain barrier. The anti-tumor effect is associated with the ability of fenoterol and related analogues to induce production of cyclic adenosine monophosphate (cAMP), which is normally decreased in glioblastomas and astrocytomas. Induced cAMP production inhibits brain tumor growth in vivo. Fenoterol and related analogues are beta-2 adrenergic receptor (β2 AR) agonists and the anti-tumor effect is associated with the expression of this receptor. Since there is a heterogeneous expression of β2 AR in human brain tumors, patients who will respond to fenoterol therapy can be predetermined leading to individualized treatment. In addition to use in the initial treatment of brain tumors, the systemic and CNS bioavailability of the drug after oral