417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

VESANOID (tretinoin) Capsules, 10 mg, are the subject of NDA 20–438, held by Hoffman-La Roche Inc. (Roche), and initially approved on November 22, 1995. VESANOID is indicated for the "induction of remission in patients with acute promyelocytic leukemia (APL), French-American-British (FAB) classification M3 (including the M3 variant), characterized by the presence of the t(15;17) translocation and/or the presence of the PML/RARα [promyelocytic leukemia/retinoic acid receptor alpha] gene who are refractory to, or who have relapsed from, anthracycline chemotherapy, or for whom anthracycline-based chemotherapy is contraindicated" (VESANOID labeling).

In a letter dated December 2, 2009, Roche notified FDA that VESANOID (tretinoin) Capsules, 10 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. There is one approved ANDA for tretinoin capsules, 10 mg (ANDA No. 77–684); this drug product is listed in the Orange Book and, following the discontinuation of VESANOID, was designated as the reference listed drug to which new ANDAs should refer.

Rakoczy Molino Mazzochi Siwik LLP submitted a citizen petition dated March 17, 2010 (Docket No. FDA–2010–P–0157), under 21 CFR 10.30, requesting that the agency determine whether VESANOID (tretinoin) Capsules, 10 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA has determined under § 314.161 that VESANOID (tretinoin) Capsules, 10 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that VESANOID (tretinoin) Capsules, 10 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of VESANOID (tretinoin) Capsules, 10 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the agency will continue to list VESANOID (tretinoin) Capsules, 10 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of the approved ANDA that refers to VESANOID. Additional ANDAs for tretinoin capsules, 10 mg, may also be approved by the agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: September 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–22807 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–D–0462]

Draft Guidance for Industry on Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment." The purpose of this guidance is to assist sponsors in all phases of development of direct-acting antiviral agents (DAAs), defined as agents that interfere with specific steps in the hepatitis C virus (HCV) replication cycle. The guidance outlines the types of nonclinical studies and clinical trials recommended throughout the drug development process to support approval of treatments for chronic hepatitis C (CHC), including in patients with compensated and decompensated cirrhosis and those co-infected with human immunodeficiency virus (HIV). The guidance also addresses pre-approval access in the form of treatment investigational new drug applications (INDs) and intermediate-sized safety protocols.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 15, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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: 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).