infestation; malignancy of pancreas or bowel; or folic acid deficiency.

In a letter dated December 21, 2016, Fresenius notified FDA that CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, was discontinued over 30 years ago, and Fresenius had concluded that the drug was discontinued for reasons other than safety or effectiveness. Fresenius also conveyed that they currently manufacture and market a 1 milliliter multiple dose vial of the 1 milligram per milliliter concentration.

John R. Rapoza submitted a citizen petition dated June 16, 2016 (Docket No. FDA–2016–P–1676), under 21 CFR 10.30, requesting that the Agency determine whether CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will list CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, 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 approved ANDAs that refer to this drug product. Additional ANDAs for this drug product 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: March 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05246 Filed 3–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances for Rifaximin; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a revised draft guidance for industry on generic rifaximin oral tablets entitled ''Draft Guidance on Rifaximin.'' The revised draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for rifaximin oral tablets.

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 May 15, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance on Rifaximin.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more

information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific guidances available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a revised draft guidance for generic rifaximin oral tablets.

FDA initially approved new drug application (NDA) 021361 for XIFAXAN (rifaximin oral tablets) 200 milligram (mg) in May 2004 and NDA 022554 for XIFAXAN (rixaximin oral tablets) 550 mg in March 2010. In November 2011, FDA issued a draft guidance for industry on generic 200 mg rifaximin oral tablets; in February 2012, FDA issued a draft guidance for industry on generic 550 mg rifaximin oral tablets. We are now consolidating these two guidances and issuing a single revised draft guidance for industry on generic rifaximin oral tablets (''Draft Guidance on Rifaximin'').

In May 2008, Salix Pharmaceuticals, Inc. (Salix), manufacturer of the reference listed drugs XIFAXAN 200 mg and XIFAXAN 550 mg, submitted a citizen petition requesting that FDA refrain from approving any ANDA referencing XIFAXAN 200 mg unless certain conditions were satisfied, including conditions related to demonstrating BE. In October 2016, Baker & Hostetler LLP submitted a citizen petition on behalf of Salix requesting that FDA refrain from approving any ANDA referencing XIFAXAN 200 mg or XIFAXAN 550 mg unless certain conditions were satisfied, including conditions related to demonstrating BE. FDA has reviewed the issues raised in these citizen petitions and is responding to the citizen petitions separately in the dockets for those citizen petitions (Docket Nos. FDA–2008–P–0300 and FDA–2016–P–3418, available at *https://www.regulations.gov*).

The revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on ''Draft Guidance on Rifaximin.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

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

Dated: March 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05245 Filed 3–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number: HHS–2017–IHS–HLY–0001; Catalog of Federal Domestic Assistance Number: 93.933]

Healthy Lifestyles in Youth Project; Proposed Single Source Competing Continuation Cooperative Agreement with National Congress of American Indians

Key Dates

Application Deadline Date: May 15, 2017
Review Date: May 22–26, 2017
Earliest Anticipated Start Date: September 1, 2017
Proof of Non-Profit Status Due Date: May 15, 2017

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Clinical and Preventive Services, Division of Diabetes Treatment and Prevention, is accepting applications for a single source competing continuation cooperative agreement with the National Congress of American Indians (NCAI) for the purpose of continued implementation of the Healthy Lifestyles in Youth Project in selected Native American Boys and Girls Clubs of America. This program is authorized under the authority of the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001; and the Public Health Service Act, as amended, 42 U.S.C. 241(a). This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

Background

This program promotes healthy lifestyles among American Indian and Alaska Native (AI/AN) youth using the curriculum ''Together Raising Awareness for Indian Life'' (TRAIL) among selected Boys and Girls Club sites. Under this cooperative agreement, IHS proposes to enter into a collaborative effort/initiative with NCAI, because of their unique experience partnering with the IHS and Boys and Girls Clubs of America (BGCA) in successfully establishing this program, as well as, their overall expertise and experience in addressing and evaluating healthy lifestyle techniques in AI/AN youth.

Purpose

This work will continue to support the IHS mission to improve the health of AI/AN youth through health