importers, who will have more responsibility for the safety of imported foods.

Beyond FSMA's implementation, the FVM Program Strategic Plan provides details on our goals of protecting and enhancing the health of people and animals. The active engagement of all stakeholders and partners, both internal and external, is critical to the successful implementation of this plan.

II. Electronic Access

Persons with access to the Internet may obtain the FVM Program Strategic Plan at *http://www.regulations.gov.*

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA Foods and Veterinary Medicine Program Strategic Plan, FY 2016–2025, available at *http://www.fda.gov/aboutfda/centersoffices/officeoffoods/ucm273269.htm.*
2. Partnership for Food Protection (PFP) Strategic Plan FY 2015 through 2020, available at *http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM423834.pdf.*

Dated: July 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16684 Filed 7–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1659]

Bacterial Vaginosis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Bacterial Vaginosis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of bacterial vaginosis (BV).

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 12, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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–2016–D–1659 for ''Bacterial Vaginosis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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 *http://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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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.

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 document.

FOR FURTHER INFORMATION CONTACT: Edward Weinstein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6382, Silver Spring, MD 20993–0002, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bacterial Vaginosis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of BV. This draft guidance helps define enrollment criteria for BV trials and recommends that such trials be superiority trials. The draft guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of BV, including the characterization of the primary efficacy endpoint.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs. In 1998, FDA published a draft guidance entitled ''Bacterial Vaginosis—Developing Antimicrobial Drugs for Treatment'' (the 1998 draft guidance). In a **Federal Register** notice dated August 7, 2013 (78 FR 48175), FDA announced an initiative in the Center for Drug Evaluation and Research involving the review of draft guidance documents issued before 2010 to determine their status and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. In the August 7, 2013, **Federal Register** notice, FDA announced that the 1998 draft guidance, as well as other draft guidances, was being withdrawn (78 FR 48175). FDA is now issuing a new draft guidance that revises the recommendations in the 1998 draft guidance.

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 current thinking of FDA on this topic. 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. 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

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

Dated: July 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16636 Filed 7–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Announcement of Requirements and Registration for ''Blockchain and its Emerging Role in Health IT and Health-related Research''; Amendment

AGENCY: Office of the National Coordinator for Health Information Technology, HHS. *Award Approving Official:* Karen DeSalvo, National Coordinator for Health Information Technology.

ACTION: Notice; Amendment.

SUMMARY: This document amends the notice published in **Federal Register**, Friday July 8, 2016, volume 81, pages 44639–44640. This notice updates and extends the submission period to August 8, 2016, limits an investigator or co-investigator to one submission and adds prize details. The ''Use of Blockchain in Health IT and Health-related Research'' Ideation Challenge solicits white papers on the topic of Blockchain Technology and the potential use in Health IT to address privacy, security and scalability challenges of managing electronic health record and resources. Up to 15 winners will be awarded a cash prize and up to 8 winners may be invited to present their papers at an upcoming industry-wide workshop co-hosted with the National Institute of Standards and Technology (NIST). The statutory authority for this Challenge is section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

DATES:

- Submission period begins: July 7, 2016.
- Submission period ends: August 8, 2016.
- Evaluation begins: August 9, 2016.
- Evaluation ends: August 19, 2016.
- Winners notified: August 22, 2016.
- Winners Announced: August 29, 2016.
- Winner Presentation: September 26–27, 2016.

FOR FURTHER INFORMATION CONTACT: Debbie Bucci, *debbie.bucci@hhs.gov* (preferred), (202) 690–0213.

SUPPLEMENTARY INFORMATION:

Subject of Challenge

A Blockchain is a data structure that can be timed-stamped and signed using a private key to prevent tampering. There are generally three types of Blockchain: Public, private and consortium. Potential uses include:

- Digitally sign information,
- Computable enforcement of policies and contracts (smart contracts),
- Management of Internet of Things devices,
- Distributed encrypted storage, and
- Distributed trust.

This Ideation Challenge solicits White Papers on the topic of Blockchain Technology and the Potential for Its Use in Health IT and/or Healthcare Related Research Data. This nationwide call may be addressed by an individual investigator or an investigator team. Interested parties should submit a White Paper no longer than 10 pages describing the proposed subject. Investigators or co-investigators may only participate in one submission. Up to 15 of these submissions will be selected as winners. The selection of a White Paper may also result in an invitation to present at an upcoming industry-wide workshop on September 26th–27th, 2016, at NIST Headquarters in Gaithersburg, MD.

Objective

The goal of this Ideation Challenge is to solicit White Papers that investigate the relationship between Blockchain technology and its use in Health IT and/or Health Related research. The paper should discuss the cryptography and underlying fundamentals of Blockchain technology, examine how the use of Blockchain can advance industry interoperability needs expressed in the ONC's Shared Nationwide Interoperability Roadmap, as well as for Patient Centered Outcomes Research (PCOR), the Precision Medicine