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.)


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Bacterial Vaginosis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Bacterial Vaginosis: Developing Drugs for Treatment.”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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 12, 2016.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 reviewing 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.
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 and Health-related Research.

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 time-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