Page 9 – Dr. Frieden, Centers for Disease Control and Prevention

The emergency use of the authorized Trioplex rRT-PCR as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: April 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09370 Filed 4–21–16; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0321]

Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice entitled ''Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments'' that appeared in the **Federal Register** of March 4, 2016. The notice requested scientific data, information, and comments that would assist in the development of a risk assessment for produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin (including raw manure). We are taking this action for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by July 5, 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–N–0321 for ''Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments.'' 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.

FOR FURTHER INFORMATION CONTACT: Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2927.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 4, 2016 (81 FR 11572), we published a notice entitled ''Risk Assessment of Foodborne Illness Associated with Pathogens from Produce Grown in Fields Amended with Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments.'' The notice requested scientific data, information, and comments that would assist us in our plan to develop a risk assessment for produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin (BSAAO) (including raw manure). The risk assessment will evaluate and, if feasible, quantify the risk of human illness associated with consumption of produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin that are potentially contaminated with enteric pathogens, such as *Escherichia coli* O157:H7 or *Salmonella.* The risk assessment also will evaluate the impact of certain interventions, such as use of a time interval between application of the soil amendment and crop harvest, on the predicted risk. The risk assessment is intended to inform policy decisions with regard to produce safety.

We received multiple requests for an extension of the comment period. The requests conveyed concern that the original 60-day comment period does not allow sufficient time to provide the scientific data, information, and comments described in the notice. We have considered the requests and are extending the comment period for the notice until July 5, 2016. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: April 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09367 Filed 4–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Intent To Establish the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 and Solicitation of Nominations for Membership; Correction

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: In the **Federal Register** notice first published on March 17, 2016, on page 14455, and corrected on April 12, 2016, on page 21581, the U.S. Department of Health and Human Services announced its intent to establish the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 (Committee) and invited nominations for membership. The nomination period is scheduled to end at 6:00 p.m. on April 18, 2016. The notice is being amended to extend the solicitation period for nominations for two weeks to allow more time for interested individuals to submit nominations.

FOR FURTHER INFORMATION CONTACT: Emmeline Ochiai, email address: *HP2030@hhs.gov.*

Correction

In the **Federal Register**, dated March 17, 2016, on page 14455, correct the **DATES** section to read:

Nominations for membership to the Committee must be submitted by 6:00 p.m. Eastern Time on May 2, 2016.

Dated: April 13, 2016.

Donald Wright,

Deputy Assistant Secretary for Health, Disease Prevention and Health Promotion.

[FR Doc. 2016–09132 Filed 4–21–16; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel NTU 2016.

Date: May 18–19, 2016.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, Room 1066, 6701 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Barbara J. Nelson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational, Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1080, Bethesda, MD 20892–4874, 301–435–0806, *nelsonbj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)