

residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora. The objectives of this guidance are to: (1) Outline the steps in determining the need for establishing a microbiological acceptable daily intake (ADI); (2) recommend test systems and methods for determining no-observable adverse effect concentrations (NOAECs) and no-observable adverse effect levels (NOAELs) for the endpoints of health concern; and (3) recommend a procedure to derive a microbiological ADI. It is recognized that different tests may be useful. The experience gained with the recommended tests may result in future modifications to this guidance and its recommendations.

III. Significance of Guidance

This guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." In addition, guidance documents must not include mandatory language such as "shall," "must," "require," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement.

This guidance represents the Agency's current thinking on this topic. 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.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 this guidance have been approved under OMB control number 0910–0032.

V. 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. 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.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: February 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05016 Filed 3–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1153]

Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA To Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food; Request for Comments and for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and information.

SUMMARY: In September 2011, the Food and Drug Administration (FDA or the Agency) asked the Institute of Food Technologists (IFT) to execute product tracing pilot projects as described in the FDA Food Safety Modernization Act (FSMA). FDA recently released a report from IFT on these pilot projects, entitled "Pilot Projects for Improving Product Tracing along the Food Supply System." FDA is announcing the opening of a docket to provide stakeholders and other interested parties an opportunity to submit comments and information that will help the Agency as it forms its own recommendations, to be contained in the Agency's report to Congress, and as it implements the FSMA provisions relating to the tracking and tracing of food.

DATES: Submit electronic or written comments and information by April 4, 2013.

ADDRESSES: You may submit comments and information, identified by Docket No. FDA–2012–N–2012–N–1153, by any of the following methods:

Electronic Submissions

Submit electronic comments and information in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments and information.

Written Submissions

Submit written submissions in the following way:

- **Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–N–1153 for this notice. All comments and information received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments and information, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments and information received, go to <http://www.regulations.gov> and insert the docket number(s), 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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Sherri A. McGarry, Office of Foods, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1212, Silver Spring, MD 20903, 301–796–3851.

SUPPLEMENTARY INFORMATION:

I. Background

A. FSMA Provisions Regarding Enhanced Tracking and Tracing of Food and Recordkeeping

On January 4, 2011, the President signed FSMA (Pub. L. 111–353) into law. Section 204 of FSMA, 21 U.S.C. 2223, relates to enhanced tracking and tracing of food and recordkeeping. As part of this provision, FDA must, among other things, complete the following:

1. Establish pilot projects in coordination with the food industry to explore and evaluate methods for rapid and effective tracking and tracing of foods. FDA is required to submit a report to Congress on the findings of the pilot projects together with FDA's recommendations for improving tracking and tracing of food;
2. Assess the costs and benefits associated with the adoption and use of several product tracing technologies and the feasibility of such technologies for different sectors of the food industry (including small businesses);
3. To the extent practicable in assessing the costs, benefits, and

feasibility of several product tracing technologies, evaluate domestic and international product tracing practices; consider international efforts and compatibility with global tracing systems, as appropriate; and consult with a diverse and broad range of experts and stakeholders;

4. Establish within FDA, as appropriate, a product tracing system to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food;

5. Publish a notice of proposed rulemaking to establish additional recordkeeping requirements for high risk foods;

6. Designate high-risk foods for which the additional recordkeeping requirements are appropriate and necessary to protect the public health. The list of high-risk foods is to be published on FDA's Internet Web site when the Agency issues the final rule establishing additional recordkeeping requirements for high-risk foods; and

7. Issue a small entity compliance guide within 6 months after the final rule is issued.

B. FSMA Provisions Directing FDA To Establish Pilot Projects To Explore and Evaluate Methods for Rapid and Effective Tracking and Tracing of Foods

Under section 204(a) of FSMA, in September 2011, FDA established pilot projects in coordination with the food industry to explore and evaluate methods for rapid and effective tracking and tracing of foods. These product tracing pilots were executed through an existing contract with the IFT. IFT was required to:

1. Conduct two food product tracing pilot projects—one in coordination with the processed food sector and one in coordination with the produce sectors—working in consultation with the U.S. Department of Agriculture, State public health agencies, and nongovernmental organizations that represent the interests of consumers;

2. Conduct the pilot projects to reflect the diversity of the food supply and consider/address confounding factors, such as commingling and transshipment;

3. Include different types of FDA-regulated foods that were the subject of significant outbreaks between 2005 and 2010;

4. Use the selected foods to develop and demonstrate methods for rapid and effective tracking and tracing of foods that are practical for facilities of varying sizes, including small businesses;

5. Use the selected foods to demonstrate appropriate technologies that enhance the tracking and tracing of

foods along the supply chain from source to points of service;

6. Demonstrate the tracking and tracing of: (a) A selected processed food and its key ingredients (minimum of two ingredients) and (b) a selected fruit and/or vegetable along the supply chain;

7. Assess the costs and benefits of the methods for rapid and effective tracking and tracing of the selected foods and key ingredients; and

8. Determine the feasibility of product tracing technologies for different sectors of the food industry, including small businesses.

FDA released the report containing the findings of the pilot projects, entitled "Pilot Projects for Improving Product Tracing along the Food Supply System" in March 2013. The report is available on FDA's Product Tracing Web page at <http://www.fda.gov/Food/FoodSafety/FSMA/ucm270851.htm>. This extensive report is being reviewed by FDA. After careful review of this report and information previously gathered, FDA will submit its report to Congress containing FDA recommendations for improving product tracing. This docket is being opened in order to request comments on the pilot project report's findings and recommendations to help inform FDA in preparing its recommendations in the Agency's report to Congress.

C. Request for Comments and Information

In addition to providing the findings of the pilot projects, the report contains IFT's recommendations for FDA on improving tracking and tracing of food. FDA released this report to make it available for stakeholders and to solicit input that may be helpful as FDA forms its own recommendations, to be contained in the Agency's report to Congress, and as FDA implements other FSMA requirements related to product tracing. FDA invites comment on the findings and recommendations contained in the IFT report and the submission of information relevant to improving product tracing. In addition, FDA would like specific comment on the following:

1. The report contains specific recommendations regarding key data elements (KDEs) and critical tracking events (CTEs). How might this work for your industry segment? What would you keep the same or change in Table 2 in the Executive Brief of the report? Please include an explanation of why you would keep the same or change.

2. The report recommends that all foods be covered, not just high-risk foods. The rulemaking requirement in section 204(d) of FSMA only refers to

high-risk foods. Should FDA pursue implementation of some or all of the report's recommendations with respect to all foods, not just high-risk foods? If so, what routes might the Agency use?

3. The report recommends that each member of the food supply chain should be required to develop, document, and exercise a product tracing plan. FDA is aware that industry often conducts and documents recall exercises, which are essentially traceforward exercises. Is it feasible to add a traceback to existing procedures and exercises? Should FDA include this IFT recommendation as one of its recommendations in the Agency's report to Congress? Please explain why the FDA should or should not include.

4. What additional information and data sources could be used to determine cost and benefits associated with implementing IFT's recommendations for KDEs and CTEs?

5. How might FDA more clearly and consistently articulate the information it needs to conduct product tracing investigations? Would posting information on FDA's Web site on how FDA typically conducts a traceback or traceforward be helpful?

6. The report recommends that FDA develop standardized electronic mechanisms for the reporting and acquiring of CTEs and KDEs during product tracing investigations. How would this work for your industry segment? How might it be achieved most expeditiously?

7. Is there anything else FDA should consider in preparing its recommendations for improving product tracing in the Agency's report to Congress?

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

III. References

The following reference has 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 is available electronically at <http://www.regulations.gov>.

1. McEntire, Jennifer and Bhatt, Tejas, "Pilot Projects for Improving Product Tracing Along the Food Supply System—Final Report," *Institute of Food Technologists*, August 2012.

Dated: February 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-04997 Filed 3-4-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 07, 2013, 10:00 a.m. to 4:00 p.m. EDT.

Place: Audio Conference Call.

The ACCV will meet on Thursday, March 7, from 10:00 a.m. to 4:00 p.m. (EDT). The public can join the meeting via audio conference call by dialing 1-800-369-3104 on March 7 and providing the following information:

Leader's Name: Dr. Vito Caserta.

Password: ACCV.

Agenda: The agenda items for the March meeting will include, but are not limited to: Updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (<http://www.hrsa.gov/vaccinecompensation/accv.htm>) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857 or email: aherzog@hrsa.gov. Requests should contain the name, address, telephone number, email address, and any business or

professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by email, mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

For Further Information Contact:

Anyone requiring information regarding the ACCV should contact Annie Herzog, DVIC, HSB, HRSA, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-6593 or email: aherzog@hrsa.gov.

Dated: February 26, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013-04953 Filed 3-4-13; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 78 FR 956-957, dated January 7, 2013).

This notice reflects organizational changes to the Health Resources and Services Administration. This notice updates the functional statement for the Office of Federal Assistance Management (RJ). Specifically, this notice: (1) Moves the grant officer and loan officer function from the Office of the Associate Administrator (RJ) to the Division of Grants Management Operations (RJ3); and (2) moves the electronic grant management system function from the Division of Grants Management Operations (RJ3) to the Office of the Associate Administrator (RJ).

Chapter RJ—Office of Federal Assistance Management

Section RJ-20, Functions

(1) Delete the functional statement for the Office of the Associate Administrator (RJ) and the functional statement for the Division of Grants Management Operations (RJ3), and replace in their entirety.

Office of Federal Assistance Management (RJ)

Provides national leadership in the administration and assurance of the financial integrity of HRSA's programs and provides oversight over all HRSA activities to ensure that HRSA's resources are being properly used and protected. Provides leadership, direction, and coordination to all phases of grants policy, administration, and independent review of competitive grant applications. Specifically: (1) Serves as the Administrator's principal source for grants policy and financial integrity of HRSA programs; (2) exercises oversight over the Agency's business processes related to assistance programs; (3) facilitates, plans, directs, and coordinates the administration of HRSA grant policies and operations; (4) directs and carries out the independent review of grant applications for all of HRSA's programs; (5) exercises the sole responsibility within HRSA for all aspects of grant and cooperative agreement receipt, award, and post-award processes; and (6) provides oversight of the management and maintenance of, and enhancements to, the electronic grant management system that enables staff to perform their day-to-day work.

Division of Grants Management Operations (RJ3)

(1) Plans, directs and carries out the grants officer functions for all of HRSA's grant programs as well as awarding official functions for various scholarship, loan, and loan repayment assistance programs; (2) participates in the planning, development, and implementation of policies and procedures for grants and cooperative agreements; (3) provides assistance and technical consultation to program offices and grantees in the application of laws, regulations, policies, and guidelines relative to the Agency's grant and cooperative agreement programs; (4) develops standard operating procedures, methods, and materials for the administration of the Agency's grants programs; (5) establishes standards and guides for grants management operations; (6) reviews grantee financial status reports and prepares reports and