recommendations on how to accurately use these terms in an ANDA, how persons can request FDA designation of an RLD, and how persons can request FDA selection of a reference standard.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Referencing Approved Drug Products in ANDA Submissions. 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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00820 Filed 1–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4662]

Public Hearing: Strategic Partnerships To Enhance the Safety of Imported Foods: Capacity Building, Risk-Based Decisionmaking, Recognition of Commodity Food Control Programs, and Systems Recognition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a public hearing regarding FDA initiatives for enhancing the safety of foods (for humans and animals) imported into the United States. The hearing will focus on partnerships to improve safety capabilities through capacity building; partnerships that incorporate information from private entities and foreign competent authorities to inform risk-based decisionmaking; partnerships that recognize commodity-specific export programs; and partnerships that recognize the robustness of a nation's entire food safety system. In addition, we are seeking information from a variety of viewpoints, including from competent authorities in other countries and from private entities, to help inform FDA regarding risk-based decisionmaking, commodity-specific export control programs in other countries, and systems recognition.

DATES: See ''How to Participate in the Hearing'' in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meetings, closing dates for advance registration, requesting special accommodations due to disability, closing date to submit comments to the docket, and other information regarding meeting participation.

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–2016–N–4662 for ''Public Hearing: Strategic Partnerships to Enhance the Safety of Imported Foods: Capacity Building, Risk-Based Decisionmaking, Recognition of Commodity Food Control Programs, and Systems Recognition.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' 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.'' We will review this copy, including the claimed confidential information, in our 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: *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 *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.

FOR FURTHER INFORMATION CONTACT: Wade Woolfolk, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–550), 5001

Campus Dr., College Park, MD 20740, 240–402–6411, FAX: 301–436–2618, email: *wade.woolfolk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 30–31, 2011, we held a public hearing to discuss our use of international comparability assessments as a mechanism to help enhance the safety of imported foods (see ''Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries; Public Hearing; Request for Comments'' (76 FR 13638, March 14, 2011; available at *https://www.regulations.gov,* in docket FDA–2011–N–0135)). At the public hearing we presented information on our food safety capacity building efforts related to the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). We also held a public meeting on June 19, 2012, to discuss our comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries in countries that export foods to the United States (see ''International Capacity Building with Respect to Food Safety Public Meeting'' (77 FR 30017, May 21, 2012; available at *https://www.regulations.gov,* in docket FDA–2011–N–0135)). This meeting invited discussion on the International Capacity Building plan development under FSMA. Following these discussions we issued the final International Capacity Building Plan in February 2013. See *http://www.fda.gov/food/guidanceregulation/fsma/ucm301708.htm.*

FSMA has enabled us to better protect public health through new authorities to help ensure that imported foods meet the same safety standards as foods produced in the United States.

In implementing FSMA, we recognize the importance of strengthening the existing collaborations among food safety regulators (U.S. Federal, State, local, territorial, tribal, and foreign) to achieve our public health goals. We continue to engage in a variety of partnerships that, collectively, are intended to enhance the safety of foods imported into the United States.

At the public hearing that is the subject of this notice, we will provide an update on our food safety capacity building efforts, as well as additional updates and information on the approach we will use to help ensure the safety of imported foods. In addition, the public hearing will provide an opportunity for FDA to obtain testimony from diverse stakeholder groups as we seek to develop, expand, or refine key partnership activities.

We seek input from a variety of perspectives on the following topics:

- How to expand performance measurement for FDA's capacity building activities to ensure that we collaborate effectively with other nations, multilateral organizations, donor organizations, and industry.
- How to operationalize the concept of ''same level of public health protection'' that is part of the rule on Foreign Supplier Verification Programs (FSVP) (80 FR 74226, November 27, 2015) and what types of partnerships facilitate application of this concept. (The FSVP regulation requires importers to implement FSVPs to provide adequate assurances that the importer's foreign suppliers produce food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under section 418 (concerning hazard analysis and preventive controls) or 419 (concerning produce safety) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as appropriate, and in compliance with sections 402 (concerning adulteration) and 403(w) (concerning misbranding regarding allergen labeling) of the FD&C Act.)
- Whether and how we should consider private standards in risk-based decisionmaking, including how other competent authorities use information, such as third-party certifications or other assurances, from private entities.
- Whether and how we should expand our systems recognition framework to include consideration of the recognition of commodity-specific export control programs.

The initiatives that will be discussed at the public hearing align with and support FSMA implementation. Day one of the hearing will seek input on partnerships to improve food safety capabilities in other countries, tools to inform FDA's risk based decisionmaking, and methods to assess the effectiveness of our capacity building efforts. We also seek input on whether and how best to incorporate input from private entities and other competent authorities into our risk-based decisionmaking framework. Day two will seek input on partnerships that recognize the robustness of commodity-specific export programs including export certification programs and whether and how we should consider such programs. In addition, we seek input on the implementation of the systems recognition program. Interested parties may submit comments, data, and supporting information on the issues described in part II of this document.

II. Purpose and Format of the Public Hearing

A. Day One of Hearing

1. Partnerships To Improve Food Safety Capabilities: International Capacity Building

Section 305 of FSMA requires the Secretary of Health and Human Services to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States. This authority was delegated to FDA, and we developed an International Food Safety Capacity Building Plan (the Plan). The Plan gives us a strategic framework to expand the technical, scientific, and regulatory capacity of foreign governments and their food industries. We developed the Plan in consultation with many partners, such as officials from other parts of the U.S. government; foreign government officials; non-governmental organizations (NGOs) that represent consumer interests; food industry representatives; and others. We seek input on successful models for continuing capacity building to further implement the plan. At this hearing, we will seek comment on food safety capacity building and development and invite comment, particularly publications and data, on food safety performance monitoring regimes; how donor organizations minimize duplication and support leveraged partnerships; how providers of training programs assure affordable, accessible, and culturally specific information is available to various regions of the world; how development agencies interface with food industry supply chain management programs; and whether we and industry can leverage each other's efforts.

2. Partnerships To Incorporate Information From Competent Authorities and Private Entities To Inform Risk-Based Decisionmaking

In the **Federal Register** of November 27, 2015 (80 FR 74570), we published a final rule entitled, ''Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications.'' The final rule established a voluntary program for the accreditation of third-party certification bodies to conduct food safety audits of foreign food facilities and to issue food and facility certifications. The requirements in the final rule will help

ensure the competence and independence of the accreditation bodies and third-party certification bodies participating in the program. We are aware that other countries incorporate information from private entities into their regulatory decisionmaking. We are interested in learning more about the policies, practices, and programs used by foreign regulators to ensure the safety of food imported into their countries. We seek comment and examples on how other countries use information from private entities; how other countries ensure parity in audit, inspectional, verification, and overall oversight between domestic and import activities; and how transparency can be best achieved.

B. Day Two of Hearing

1. Partnerships That Recognize Commodity-Specific Exports and Programs

We are interested in identifying successful models that recognize commodity specific food safety control systems (including export certification programs), how they are established, and how they operate.

We seek comment and views on the best practices, strengths and weaknesses of commodity export programs or export certification systems; how commodity recognition programs factor into risk-based inspectional systems; and once adopted, how the programs are monitored over time.

2. Partnerships That Recognize the Robustness of the Entire Food Safety System: Systems Recognition

FDA's systems recognition assessment process established in 2011 has progressed from a pilot to a robust program that has resulted in signed arrangements with New Zealand's Ministry for Primary Industries (2012) and Canada's Canadian Food Inspection Agency (CFIA) and the Department of Health Canada (Health Canada) (2016). We seek comment on what indicators we should consider to determine whether the program meets expected outcomes and best practices on how to identify robust food safety systems.

III. Notice of Hearing Under Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer(s), accompanied by FDA senior management and staff from the relevant centers/offices (FDA panelists/experts).

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. We encourage interested parties to submit comments to the docket. We also have invited certain members of the public to participate as guest presenters. Only the presiding officer(s) and FDA panelists/experts may question any person during or at the conclusion of each presentation by the FDA and guest presenters (§ 15.30(e)). At their discretion, the presiding officer(s) may permit questions to be submitted from the audience for response by FDA or other persons attending the hearing (§ 15.30(e)). Finally, time permitting, stakeholders may be allowed to provide testimony at the hearing. Time will be limited to 2 minutes and requests to make an oral presentation must be written and received by February 8, 2017. Please include the details of your presentation when making your request. All testimony will be entered into the docket. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see part IV of this document). To the extent that the conditions for the hearing as described in this document conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Comments may also be submitted after the hearing. The docket will remain open for such comments until May 16, 2017.

IV. How To Participate in the Public Hearing

Advance registration by submission of a notice of participation is necessary to ensure participation and will be accepted on a first-come, first-served basis.

Notices of participation may be submitted electronically (see table 1 of this document); FDA encourages the use of electronic means of advance registration. Notices of participation may also be submitted orally or by mail, fax, or email (see **FOR FURTHER INFORMATION CONTACT**). See table 1 of this document for the dates by which notices of participation must be submitted. A single copy of any notice of participation is sufficient.

Table 1 of this document provides information on participation in the public meetings.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING

Activity	Date	Electronic address	Address	Other information
Attend Public Hearing	February 14–15, 2017, from 9 a.m. to 5:00 p.m.	Please preregister at *www.fda.gov/Food/NewsEvents/Workshops/Meetings/Conferences/default.htm*.	FDA Center for Food Safety and Applied Nutrition, Wiley Auditorium, 5001 Campus Dr., College Park, MD 20740.	Registration check-in begins at 8 a.m.
View Webcast	February 14–15, 2017, from 9 a.m. to 5:00 p.m.	Individuals who wish to participate by Webcast are asked to preregister at *www.fda.gov/Food/NewsEvents/WorkshopsMeetings/Conferences/default.htm*.	We encourage you to use electronic registration if possible.	The Webcast will have closed captioning.
Advance registration	Register by February 8, 2017.	*www.fda.gov/Food/NewsEvents/Workshops/Meetings Conferences/default.htm*.	We encourage you to use electronic registration if possible [1].	There is no registration fee for the public hearing. Early registration is recommended because seating is limited.[1]

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING—Continued

Activity	Date	Electronic address	Address	Other information
Request to make an oral presentation.	Request by February 8, 2017.	Individuals who wish to make a public comment during the designated times in the hearing are asked to submit request and presentation at *IASEvents@fda.hhs.gov*.	See **FOR FURTHER INFORMATION CONTACT**.	
Submitting either electronic or written comments.	Submit all other comments by May 16, 2017.	*https://www.regulations.gov*	Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See **ADDRESSES** for information on submitting comments.
Request special accommodations due to a disability.	Request by February 8, 2017.	Wade Woolfolk, email: *wade.woolfolk@fda.hhs.gov*.	See **FOR FURTHER INFORMATION CONTACT**.	

[1] Onsite registration will not be available at the meeting site.

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on FDA's Web site at *http://www.fda.gov.*

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00821 Filed 1–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; National Hospital Organ Donation Campaign's Activity Scorecard

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than February 16, 2017.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Hospital Organ Donation Campaign's Activity Scorecard OMB No. 0915–0373—Revision.

Abstract: HRSA's Healthcare Systems Bureau, Division of Transplantation, administers the Workplace Partnership for Life (WPFL) program under the authority of Section 377A(a) of the Public Health Service (PHS) Act, (42 U.S.C. 274f–1). The WPFL seeks to involve workplaces and other organizations in a national effort to increase the number of registered organ, eye, and tissue donors and to increase awareness about organ donation. In 2011, HRSA launched the National Hospital Organ Donation Campaign (Hospital Campaign) and issued a challenge to hospitals nationwide to assist in this effort by conducting donor education and donor registry enrollment events in their hospitals and communities. The nation's 58 organ procurement organizations (OPOs), which already work with hospitals on clinical aspects of transplantation, participate in the Hospital Campaign to provide assistance to hospitals in their service areas as they implement strategies and activities to increase the number of enrollments in state donor registries. HRSA supports the Hospital Campaign by providing communications materials, facilitating the sharing of best practices, leveraging the influence of national associations and organizations related to hospitals and organ donation as Campaign National Partners, and offering the additional incentive of national-level recognition to hospitals.

Need and Proposed Use of the Information: The Hospital Campaign's Activity Scorecard is a key component of this effort. It provides a menu of over 40 ideas for outreach activities. The Activity Scorecard also provides incentive for hospitals to participate by laying the foundation for recognition. Each activity on the programmable PDF is assigned a particular number of points based on the activity's potential for generating registrations. Recognition is awarded to hospitals that have annual points which qualify them for one of the following recognition levels: bronze, silver, gold, and platinum.

Hospitals can complete the Activity Scorecard and submit it annually via email or fax to HRSA or to their local OPO or Donate Life America (DLA) affiliate to be considered for recognition. This is a voluntary activity and hospitals may participate in the campaign without using or submitting a completed Activity Scorecard. However, most hospitals enrolled in the campaign (currently 2,038) have submitted a completed Activity Scorecard to become eligible for recognition.

Hospitals that achieve specific outlined levels are recognized annually