

INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John L. Smith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 2619, Silver Spring, MD 20993, 301-796-1757.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Incorporation of Physical-Chemical Identifiers Into Solid Oral Dosage Form Drug Products for Anticounterfeiting." For the purpose of this guidance, a PCID is a substance or combination of substances possessing a unique physical or chemical property that unequivocally identifies a drug product or dosage form as authentic and distinguishes it from counterfeits. To thwart drug product counterfeiting, pharmaceutical manufacturers have been investigating technologies that may make drug products more difficult to duplicate, including the incorporation of PCIDs into SODFs. One approach that manufacturers appear to be considering involves adding a trace amount of one or more inactive ingredients to an existing section of the dosage form (in the guidance, section is the term used for a discrete, contained solid or a layer in a solid oral dosage form). Any section can be described by its composition, the functional characteristics that distinguish it from other sections in that dosage form, and its position relative to other sections that may be present (e.g., coatings, capsule shells, encapsulated particles, a layer in a bilayer tablet, and compressed powders). A unique physical-chemical characteristic of that ingredient makes it possible to detect and authenticate legitimate dosage forms, and to identify counterfeits. Examples of substances that may be incorporated into SODFs as PCIDs include inks, pigments, flavors, and molecular taggants. Such PCIDs may allow product authentication by their presence alone or may be used to code the product identity into or onto the SODF.

This guidance provides recommendations to pharmaceutical manufacturers on the following topics: (1) Design considerations for PCIDs into SODFs, (2) supporting documentation to

be submitted in NDAs or ANDAs to address the proposed incorporation of PCIDs in SODFs, (3) supporting documentation to be submitted in postapproval submissions to report or request approval to incorporate PCIDs into SODFs, and (4) procedures for reporting or requesting approval to incorporate PCIDs into SODFs as a postapproval change. Although not addressed in this guidance, FDA is considering whether to address the incorporation of a PCID into a drug's packaging or labeling in a future guidance.

In the **Federal Register** of July 14, 2009 (74 FR 34021), FDA announced the availability of a draft guidance for industry entitled "Draft Guidance for Industry on Incorporation of Physical-Chemical Identifiers Into Solid Oral Dosage Form Drug Products for Anticounterfeiting." The notice gave interested persons an opportunity to comment by October 13, 2009. We have carefully considered the comments we received and, where appropriate, have made corrections, added information, or clarified the information in the guidance in response to the comments.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the use of PCIDs in SODF drug products to prevent counterfeiting. 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.

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 documentation in premarketing regulatory submissions recommended for applicants incorporating PCIDs into SODFs would be covered under 21 CFR 314.50 and 314.94, and the documentation in postapproval regulatory submissions would be covered under 21 CFR 314.70. This information collection has been approved under OMB control number 0910-0001. The recommendations for labeling would be covered under 21 CFR 201.57. This information collection has been approved under OMB control number 0910-0572.

III. 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. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

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

Dated: October 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0400]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2011-0014]

Approaches To Reducing Sodium Consumption; Public Meeting

AGENCY: Food and Drug Administration, HHS; Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS) and the Center for Nutrition Policy and Promotion (CNPP) are announcing a public meeting entitled "Approaches to Reducing Sodium Consumption." FDA and FSIS recently published a **Federal Register** notice that announced the establishment of dockets to obtain comments, data, and evidence relevant to the dietary intake of sodium as well as current and emerging approaches designed to promote sodium reduction. The purpose of the public meeting is to provide interested persons an opportunity to

discuss the topics raised in the earlier notice.

DATES: Submit either electronic or written comments, data, and evidence to either FDA's Division of Dockets Management or FSIS's Docket Clerk by November 29, 2011. See also "How To Participate in the Meeting" in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See Table 1 of this document for meeting location and other information regarding registration for this meeting.

FOR FURTHER INFORMATION CONTACT:

FDA: Patricia M. Kuntze, Office of

External Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5322, Silver Spring, MD 20993, 301-796-8641, Patricia.Kuntze@fda.hhs.gov.

FSIS: Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, USDA, FSIS, OPDP, LPDD Stop Code 3784, Patriots Plaza III, 8-161A, 1400 Independence Ave., SW., Washington, DC 20250-3700.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 15, 2011 (76 FR 57050), FDA and FSIS announced the establishment of dockets to obtain comments, data, and evidence that will inform future Agency activities regarding the reduction of dietary intake of sodium. FDA, CDC, FSIS, ARS, and CNPP are announcing a public meeting entitled "Approaches to Reducing Sodium Consumption" to discuss the topics raised in section II of that notice. Interested persons may also wish to review the FDA's Sodium Reduction Web page located at <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm253316.htm>.

Reducing sodium consumption is also part of the Department of Health and Human Services' (the Department's) recently-launched Million Hearts initiative (<http://millionhearts.hhs.gov/>). The Department, working with several key initial partners, is aiming to prevent one million heart attacks and strokes over the next 5 years. Among other

significant public health goals, the campaign stresses the need to identify opportunities for sodium reduction.

II. Purpose and Format of the Meeting

If you wish to attend and/or present at the meeting scheduled for November 10, 2011, please register at http://events.SignUp4.net/FDA_Sodium_Reduction by November 3, 2011. FDA, CDC, FSIS, ARS, and CNPP are holding the public meeting on sodium reduction in foods to inform possible future actions by the Agencies. In general, the meeting format will include introductory presentations by FDA, USDA, and CDC, but listening to interested persons is the primary purpose of this meeting. In order to meet this goal, FDA, CDC, FSIS, ARS and CNPP will provide multiple opportunities for individuals to express their opinions through oral presentations at the meeting, participation in break-out sessions on the issues discussed at the meeting, and submission of electronic or written comments, data, and evidence to FDA's Division of Dockets Management and/or FSIS's Docket Clerk by November 29, 2011. The break-out session topics will be available prior to the meeting on FDA's Sodium Reduction Web page at <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm253316.htm>. The plenary sessions and some of the breakout sessions will be Web cast; see section III of this document, "How to Participate in the Meeting." In order to provide Web cast participants with information before and after the meeting, we request attendees provide their name, their affiliation, and e-mail address when pre-registering for the Web cast at http://events.SignUp4.net/FDA_Sodium_Reduction.

III. How To Participate in the Meeting

Interested persons will have an opportunity to provide oral comments, time permitting. Due to limited space and time, FDA, CDC, FSIS, ARS, and CNPP encourage all persons who wish to attend the meeting onsite or via Web cast to register in advance at http://events.SignUp4.net/FDA_Sodium_Reduction. There is no

fee to register for the public meeting, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated. Table 1 of this document provides information on participating in the meeting and on submitting comments to the docket.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting, are asked to submit their request by November 3, 2011, and to provide the specific topic or issue to be addressed and the approximate desired length of their presentation. Depending on the number of requests for such oral presentations, there may be a need to limit the number and length (e.g., 3 minutes each) of the oral presentations. If time permits, individuals or organizations that did not register in advance may be granted the opportunity for such an oral presentation. FDA, CDC, FSIS, ARS, and CNPP would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting. We are especially interested in hearing about sodium reduction related research results or research efforts underway. FDA, CDC, FSIS, ARS, and CNPP anticipate that there will be several opportunities for interested persons to speak in break-out sessions. A Web cast will be available for interested persons who are not onsite. Interested persons will also have an opportunity to submit electronic or written comments to the docket following the meeting, but no later than November 29, 2011.

FDA, CDC, FSIS, ARS, and CNPP encourage persons and groups who have similar interests to consolidate their information for presentation through a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the amount of time available, the approximate time their presentation is scheduled to begin, and the presentation format.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS

	Date	Electronic address	Address (non electronic)	Other information
Date of Public Meeting.	November 10, 2011, from 9 a.m. to 5:30 p.m. EST.	Individuals who wish to participate in person are asked to pre-register at http://events.SignUp4.net/FDA_Sodium_Reduction .	FDA White Oak Campus, The Great Room, Bldg. 31, Rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993.	Registration begins at 7:30 a.m.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS—Continued

	Date	Electronic address	Address (non electronic)	Other information
Web cast	November 10, 2011, from 9 a.m. to 5:30 p.m. EST).	Individuals who wish to view the Web cast of this meeting are requested to pre-register at http://events.SignUp4.net/FDA_Sodium_Reduction . It is recommended that Web cast attendees test their Internet connection to confirm access to the Web cast prior to the meeting. To test this connection, visit http://fda.yorkcast.com/webcast/Catalog/catalogs/default.aspx and click on “CDRH Television Tutorial and Firewall Test.”.	FDA encourages the use of electronic registration, if possible.	The Web cast will provide closed captioning.
Advance Registration	Register by November 3, 2011.	http://events.SignUp4.net/FDA_Sodium_Reduction .	FDA encourages the use of electronic registration, if possible.	Registration to attend the meeting will also be accepted onsite on the day of the meeting, as space permits. Registration information may be posted without change to http://www.regulations.gov , including any personal information provided.
Request special accommodations due to disability.	Register by November 3, 2011.	Patricia M. Kuntze, 301–796–8641, e-mail: Patricia.Kuntze@fda.hhs.gov .	
Make a request for oral presentation.	Register by November 3, 2011.	http://events.SignUp4.net/FDA_Sodium_Reduction	Requests made on the day of the meeting to make an oral presentation may be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Provide a brief description of the oral presentation and any written material for the presentation.	By November 3, 2011.	http://events.SignUp4.net/FDA_Sodium_Reduction	Written material associated with an oral presentation should be submitted in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) and may be posted without change to http://www.regulations.gov , including any personal information provided.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS—Continued

	Date	Electronic address	Address (non electronic)	Other information
Submit electronic or written comments.	Submit comments by November 29, 2011.	Federal eRulemaking Portal: http://www.regulations.gov . Follow the instructions for submitting comments.	<i>FDA</i> : FAX: 301–827–6870. 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. <i>FSIS</i> : Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, George Washington Carver Center, 5601 Sunnyside Ave., Mailstop 547, Beltsville, MD 20705–5464.	All comments must include the Agency name and the docket number (see table 2 of this document for a list of Agencies and corresponding docket numbers). All received comments may be posted without change to http://www.regulations.gov , including any personal information provided. FDA and FSIS encourage the submission of electronic comments by using the Federal eRulemaking Portal. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

IV. Comments

FDA: Regardless of attendance at the public meeting, interested persons may submit to FDA’s Division of Dockets Management (see Addresses in table 1 of this document) either electronic or written comments for consideration at or after the meeting, in addition to, or in place of, a request for an opportunity to make an oral presentation. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

FSIS: Regardless of attendance at the public meeting, interested persons may submit to FSIS’s Docket Clerk (see Addresses in table 1 of this document) either electronic or written comments regarding this document. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Because two docket numbers are associated with this document, please include with your comments the docket number that corresponds with the appropriate Agency. Comments submitted for inclusion in both dockets should be separately submitted to each identified docket number to ensure consideration by both Agencies.

V. Transcripts

Please be advised that as soon as a transcript is available, it will be posted on FDA’s Sodium Reduction Web page at <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm253316.htm>. It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: October 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy, Food and Drug Administration.

Dated: October 4, 2011.

Alfred V. Almanza,

Administrator, Food Safety and Inspection Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Data and Data Needs To Advance Risk Assessment for Emerging Infectious Diseases Relevant to Blood and Blood Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: “Data and Data Needs to Advance Risk Assessment for Emerging Infectious Diseases Relevant to Blood and Blood Products.” The purpose of the public workshop is to discuss data and data sources currently used by FDA, possible new sources of data, and development of new studies and information through collaboration with stakeholders. The public workshop will include presentations and panel discussions with experts from stakeholders, academia, regulated industry, and government.

Date and Time: The public workshop will be held on November 29, 2011, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877, 301–977–8900.

Contact Person: Lou Gallagher, Center for Biologics Evaluation and Research (HFM–210), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448,