

The meeting will be available via Web cast. For additional information, go to: http://www.hhs.gov/healthit/ahic/quality/quality_instruct.html.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Confidentiality, Privacy, & Security Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the 22nd meeting of the American Health Information Community Confidentiality, Privacy, & Security Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., App.).

DATES: August 21, 2008, from 1 p.m. to 5 p.m. [Eastern Time].

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 1114. Please use the C Street entrance closest to 3rd Street and bring photo ID for entry to a Federal building.

FOR FURTHER INFORMATION CONTACT: <http://www.hhs.gov/healthit/ahic/confidentiality/>.

SUPPLEMENTARY INFORMATION: The Workgroup Members will continue discussing and evaluating the confidentiality, privacy, and security protections and requirements for participants in electronic health information exchange environments.

The meeting will be available via Web cast. For additional information, go to: http://www.hhs.gov/healthit/ahic/cps_instruct.html.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Population Health and Clinical Care Connections Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the 29th meeting of the American Health Information Community Population Health and Clinical Care Connections Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App.).

DATES: August 20, 2008, from 2 p.m. to 5 p.m. [Eastern Time].

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 1114. Please use the C Street entrance closest to 3rd Street and bring photo ID for entry to a Federal building.

FOR FURTHER INFORMATION CONTACT: <http://www.hhs.gov/healthit/ahic/population/>.

SUPPLEMENTARY INFORMATION: The Workgroup will continue its discussion on how to facilitate the flow of reliable health information among population health and clinical care systems necessary to protect and improve the public's health. The meeting will be available via Web cast. For additional information, go to: http://www.hhs.gov/healthit/ahic/population/pop_instruct.html.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0389]

Food and Drug Administration Amendments Act of 2007; Prohibition Against Food to Which Drugs or Biological Products Have Been Added; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting

comments relevant to the implementation of section 912 of the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 912 of FDAAA establishes section 301(l) in the Federal Food, Drug, and Cosmetic Act (the act), which prohibits the interstate shipment of certain foods to which an approved drug or a licensed biological product has been added. Section 301(l) also prohibits the interstate shipment of foods containing an added drug or a biological product that has been the subject of substantial clinical investigations, the existence of which has been made public. FDA requests that interested persons submit data, information, and comments that will help provide a context for the agency's decisions on implementation of this provision. To encourage responsive comments, FDA is including a series of questions for interested persons to consider in preparing comments.

DATES: Submit written or electronic comments by October 27, 2008.

ADDRESSES: Submit written comments, data, and other information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Catherine L. Copp, Center for Food Safety and Applied Nutrition (HFS-4), Food and Drug Administration, 301-436-1589, e-mail: catherine.copp@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) (FDAAA) was enacted. Section 912 of FDAAA establishes section 301(l) in the Federal Food, Drug, and Cosmetic Act (the act), 21 U.S.C. 331(l), which adds the following prohibited act to section 301.21 U.S.C. 331:

The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless--

(1) such drug or such biological product was marketed infood before any approval of the drug under section 505, before licensure of the biological product under such section 351, and before any substantial clinical