

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.	FDA: 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. FSIS: 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.

[FR Doc. 2011–26371 Filed 10–11–11; 8:45 am]

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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,

301-827-5988, e-mail: lou.gallagher@fda.hhs.gov.

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to Lou Gallagher (*see Contact Person*) by November 10, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Lou Gallagher (*see Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

Quantitative risk assessments (QRAs) are an important tool for evaluating the risks associated with new emerging infectious diseases (EIDs) that are relevant to blood and blood products and the benefits of mitigation options. QRAs make it possible for decisionmakers to develop policy for blood and blood product safety and availability using sound science and the best data and information available.

Rapid data collection, information sharing, and analyses estimating the magnitude and probability of risk can be expedited by proactively building and maintaining critical relationships both within the Center for Biologics Evaluation and Research (CBER) and with external stakeholders. In this public workshop, CBER is seeking access to accurate, reliable data on factors such as disease prevalence, incubation periods, behavioral risks associated with disease transmission, potential donor exposure risks, and susceptibility to EIDs, product handling, usage, and other factors.

Lack of data and information is a major challenge FDA faces when there is a new EID. The public workshop will: (1) Provide a forum for discussion of data used in conducting quantitative risk assessments for EIDs, (2) address approaches to facilitate the timely access to data required to evaluate public health measures designed to reduce the potential risk associated with EIDs that are relevant to blood and blood products, and (3) provide a forum for discussion of the development of new data sources and enhanced access to already existing data sources.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible on the Internet at: <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/>

[WorkshopsMeetingsConferences/](#)

[TranscriptsMinutes/default.htm](#).

Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: October 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-26295 Filed 10-11-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; *telephone:* 301-496-7057; *fax:* 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Human Phospho-Serine134 Glucocorticoid Receptor Polyclonal Antibody: Useful for the Characterization of Glucocorticoid Signaling Processes, e.g., in Cancer and Inflammation

Description of Technology: The glucocorticoid receptor (GR) functions as a hormone-dependent transcription factor that is involved in the maintenance of basal and stress-related homeostasis. Serine 134 is a newly discovered phosphorylation target on the human glucocorticoid receptor that becomes phosphorylated during stress-activating conditions such as ultraviolet irradiation, nutrient starvation, and oxidative stress. The inventors have

developed a rabbit polyclonal antibody that specifically recognizes the Ser 134 phosphorylated form of the human glucocorticoid receptor. This antibody may be particularly useful for a variety of basic research applications, such as the characterization and study of glucocorticoid signaling in cancer, inflammation, and other diseases.

The antibody is available as crude antisera and has been epitope purified; it has cross reactivity with human, rat, and mouse tissues.

Potential Commercial Applications: Western analysis, immunoprecipitation, and immunofluorescence studies.

Inventors: Amy Beckley and John Cidlowski (NIEHS).

Related Publication: Molecular and Cellular Biology, *In Press*.

Intellectual Property: HHS Reference No. E-182-2011/0—Research Tool.

Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Tara Kirby Ph.D.; 301-435-4426; tarak@nih.gov.

Collaborative Research Opportunity: The NIEHS, Molecular Endocrine Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Human Phospho-Serine134 Glucocorticoid Receptor Polyclonal Antibody. Please contact Elizabeth M. Denholm at denholme@niehs.nih.gov for more information.

Infectious Hepatitis E Virus Genotype 3 Recombinants—Prospective Vaccine Candidates and Vector System

Description of Technology: Infection by Hepatitis E virus (HEV) is a relevant health issue in a number of developing countries and it is also an emerging food-borne disease of industrialized countries. Genotype 1 and 2 infections are found exclusively in humans while genotype 3 and 4 viruses have been found not only in humans, but also swine, deer, mongoose, cattle, and rabbits. In particular, genotype 3 and 4 viruses are ubiquitously found in swine and undercooked pork is thought to be one of the sources of infection for cases of human infections in industrialized countries.

This technology is a recombinant, infectious genotype 3 HEV that has been adapted to grow in cell culture and can potentially be used to develop vaccines against HEV or as a vector system to insert exogenous sequences into HEV. The virus (strain Kernow-C1, genotype 3) originated from a chronically infected