

notify interested persons regarding their request to speak by June 9, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristine T. Khuc at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-12543 Filed 5-20-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 21, 2011, from 8:30 a.m. to 4 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College (UMUC), 3501 University Blvd. East, Hyattsville, MD 20783. The hotel's phone number is 301-985-7300.

Contact Person: Philip A. Bautista, Center for Drug Evaluation and

Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail:

AAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On June 21, 2011, the committee will discuss the supplemental biologics license application 125319, ILARIS (canakinumab), Novartis Pharmaceuticals Corp., for the following proposed indication: "ILARIS is indicated for the treatment of gouty arthritis attacks. ILARIS has also been shown to extend the time to the next attack and reduce the frequency of subsequent attacks."

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 7, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 27, 2011. Time allotted for each

presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 31, 2011.

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Dated: May 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-12544 Filed 5-20-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0238]

Preventive Controls for Registered Human Food and Animal Food/Feed Facilities; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to obtain information about preventive controls and other practices used by facilities to identify and address hazards associated with specific types of food and specific processes. FDA is establishing this docket to provide an opportunity for interested parties to provide information and share views that will inform the development of guidance on preventive controls for food facilities that

manufacture, process, pack, or hold human food or animal food/feed (including pet food).

DATES: Submit either electronic or written comments by August 22, 2011.

ADDRESSES: Submit electronic comments 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: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-2166; or Kim Young, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9207.

SUPPLEMENTARY INFORMATION:

I. Background

On March 19, 2009, President Barack Obama established a new Food Safety Working Group (FSWG), chaired by the Secretaries of the Department of Health and Human Services and the Department of Agriculture. In announcing the creation of the FSWG, the President said the group would advise him on how to upgrade U.S. food safety laws for the 21st century, foster coordination of food safety efforts throughout the Government, and ensure laws are being adequately enforced to keep the American people safe from foodborne illness (Ref. 1).

On July 1, 2009, the FSWG recommended a new public health-focused approach to food safety based on three core principles: (1) Prioritizing prevention; (2) strengthening surveillance and enforcement; and (3) improving response and recovery (Ref. 1). The FSWG emphasized the importance of setting rigorous standards for food safety and providing regulatory agencies the tools necessary to ensure that the food industry meets these standards. The FSWG also recommended that food regulators move aggressively to implement sensible measures designed to prevent food safety problems before they occur.

On January 4, 2011, President Barack Obama signed into law the FDA Food Safety Modernization Act (Pub. L. 111-353), which requires the owner, operator, or agent in charge of a facility required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) to take certain actions, including to evaluate the hazards that could affect food manufactured, processed, packed, or

held by the facility and to identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards. A written plan must be prepared to describe the procedures used by the facility to comply.

FDA is required to issue guidance with respect to hazard analysis and preventive controls. Given the diversity of registered facilities and regulated foods, FDA will use guidance to assist the food and feed industries in complying with the preventive controls regulations, when finalized. We plan to leverage, where appropriate, the best practices for hazards and controls identified by the food and feed industries for specific types of food and specific methods to manufacture, process, pack, and hold food.

Representatives of the food and feed industries have told FDA the food safety information they have developed is not proprietary and have committed to sharing with us the best practices relating to hazards and control measures they have identified. FDA is interested in making appropriate best practices relating to identified hazards and control measures for specific industry segments publicly available.

FDA is establishing a docket to provide an opportunity for interested parties to provide information and share views that will inform the development of guidance on the following: (1) Hazard identification and (2) control measures associated with specific types of food or specific methods of manufacturing, processing, packing, or holding food. FDA is particularly interested in preventive controls practices that are practical for small and very small businesses to implement.

II. Request for Comments and Information

We are requesting comments that will inform the development of guidance on the following: (1) Hazard identification (biological, chemical, radiological, and physical) and (2) control measures associated with specific types of food or specific methods of manufacturing, processing, packing, or holding food. In particular, we welcome input on any of the following general categories with respect to human food or animal food/feed (including pet food):

- Conducting a hazard analysis to determine the hazards associated with specific human food or animal food/feed and processes (e.g., the procedures used to determine potential hazards and to assess whether they are reasonably likely to occur).
- Implementing process controls (e.g., processes employed to prevent,

eliminate, or reduce to acceptable levels the occurrence of any hazards that are reasonably likely to occur).

- Validating food/feed safety controls (e.g., information on procedures used to determine that control measures are capable of controlling the identified hazards).

- Implementing sanitation controls (e.g., procedures and practices utilized to minimize the risk of contamination) for human food and animal food/feed.

- Implementing supplier controls (e.g., procedures and practices used to ensure raw materials and ingredients are safe for their intended use).

- Allergen control (human food), including procedures to ensure that ingredients are accurately declared on the label, procedures to ensure the proper label is applied to the food, and procedures and practices to prevent the unintentional incorporation of a major food allergen into a food by cross contact during manufacturing, processing, and holding food.

- Environmental monitoring for *Salmonella* and for *Listeria monocytogenes* for specific types of food facilities (e.g., ready-to-eat food facilities, pet food facilities).

- Microbiological and other testing used to help ensure the safety of specific human food and animal food/feed.

- Specific biological, chemical, radiological, and physical hazards and controls for food types such as (but not limited to) spices, nuts, ready-to-eat food, bakery products, fresh-cut produce, milk products, and medical food.

- Specific biological, chemical, radiological, and physical hazards and controls for animal food/feed including feed ingredients.

- Preventive control approaches and practices (e.g., for validation, supplier controls) that are practical for small and very small businesses to implement.

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. References

FDA has placed the following reference on display in FDA's Division of Dockets Management (see **ADDRESSES**)

and it may be seen between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

1. Food Safety Working Group, "Food Safety Working Group: Key Findings" (July 1, 2009), Available at <http://www.foodsafetyworkinggroup.gov/ContentKeyFindings/HomeKeyFindings.htm>. Accessed and printed on April 1, 2011.

Dated: May 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-12616 Filed 5-20-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Healthy Tomorrows Partnership for Children Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of a Noncompetitive Replacement Award to the University of Nevada School of Medicine, Department of Pediatrics.

SUMMARY: The Health Resources and Services Administration (HRSA) will transfer remaining Special Projects of Regional and National Significance (SPRANS) discretionary grant funds in H17MC08971 from the Southern Nevada Area Health Education Center, the current grantee of record, to the University of Nevada School of Medicine, Department of Pediatrics, in order to continue Healthy Tomorrows supported prevention and intervention services to low-income, underserved women, children and adolescents in Clark County and Southern Nevada.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: Southern Nevada Area Health Education Center.

Original Period of Grant Support: Healthy Tomorrows Partnership for Children Program—March 1, 2008 to February 28, 2013.

Replacement Awardee: The University of Nevada School of Medicine, Department of Pediatrics.

Amount of Replacement Award: \$100,000 (remaining two years of grant, Year 4 and Year 5).

Period of Replacement Award: The period of support for this award is March 1, 2011 to February 28, 2013.

Authority: Social Security Act as amended, Title V, Section 501(a)(2), (42 U.S.C. 701(a)(2)).

CFDA Number: 93.110.

Justification for the Exception to Competition: The former grantee, Southern Nevada Area Health Education Center, relinquished all grants due to financial difficulties and closure of facilities and programs. The Maternal and Child Health Bureau (MCHB) has identified the University of Nevada School of Medicine, Department of Pediatrics as the best qualified grantee for this replacement award because: the University of Nevada School of Medicine, Department of Pediatrics maintains an on-going partnership with the original grantee, the Southern Nevada Area Health Education Center; the original Project Director has a clinical appointment with the Department of Pediatrics; the Department of Pediatrics is maintaining the project despite not having access to grant funds; and obstetrical care for pregnant women occurs at a clinic jointly run by the Department of Pediatrics and the Department of Family and Community Medicine. Transferring funds to the Department of Pediatrics will not change the project as originally proposed and funded, as it still serves the intended target population, maintains partnerships with many of the community organizations discussed in the original application and proposes to enhance services with the addition of the Project Outreach Coordinator. In sum, the Department of Pediatrics has the capacity to provide an array of Healthy Tomorrows supported prevention and intervention services to the target population and to fulfill the expectations of the originally funded grant application.

This grant transfer will ensure that prevention and intervention services remain available for approximately 100 African American, Hispanic, and/or American Indian pregnant women in Clark County and Southern Nevada and their children; launch a community-wide, bi-lingual program of culturally competent public education and awareness services to recruit and enroll at least 100 women into the Nevada Care Program; and maintain the Nevada Care Program Screening Clinic to monitor the health and development of infants born to pregnant women enrolled in the program. Not ensuring continued funding to provide these services would have a substantially negative impact on the healthcare needs of this population, while continued funding to the Department of Pediatrics will ensure that these critical services remain available to address the demonstrated needs of low-income, underserved women, children and

adolescents in Clark County and Southern Nevada.

FOR FURTHER INFORMATION CONTACT:

Madhavi Reddy via e-mail at mreddy@hrsa.gov or via phone at 301-443-0754.

Dated: May 17, 2011.

Mary K. Wakefield,

Administrator.

[FR Doc. 2011-12655 Filed 5-20-11; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; 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: National Advisory Council on the National Health Service Corps (NHSC).

Dates and Times: June 22, 2011—8:30 a.m.—4:30 p.m.

June 23, 2011—8 a.m.—12 p.m.

Place: Saddlebrook Tampa, 5700 Saddlebrook Way, Wesley Chapel, FL 33543, *Phone:* 813-973-1111.

Status: The meeting will be open to the public.

Agenda: The Council is convening in Tampa, Florida, to hear NHSC program updates and to discuss evidence-based strategies for clinician retention, and a new communications tool for clinicians. A portion of the meeting will be open for public comment and questions.

For Further Information Contact: Njeri Jones, Bureau of Clinician Recruitment and Service, Health Resources and Services Administration, Parklawn Building, Room 8A-46, 5600 Fishers Lane, Rockville, MD 20857; e-mail: NJones@hrsa.gov; Telephone: 301-443-2541.

Dated: May 17, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011-12656 Filed 5-20-11; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Board of Scientific Advisors, June 20, 2011, 9 a.m. to June 21, 2011,