Advantages:
• Use of CpG oligonucleotides for prophylaxis and/or therapy

Applications:
• Vaccines for the prevention of cancer and other indications
  • Use of CpG oligonucleotides for prophylaxis and/or therapy

Advantages:
• Novel vaccine candidates
• Increased immunogenicity

Development Status: Preclinical studies have been conducted by the inventors.

Inventors: Dennis M. Klinman and Hidekazu Shiroti (NCI).


Licensing Status: Available for licensing.

Licensing Contact: Peter A. Soukas; 301–435–4646; soukas@email.nih.gov.

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Experimental Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John Hewes, Ph.D. at 301–435–3121 or hewes@mail.nih.gov for more information.

Dated: September 27, 2010.

Richard U. Rodriguez.
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–24679 Filed 9–30–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0270]

Medical Device User Fee and Modernization Act; Notice to Public of Web site Location of Fiscal Year 2011 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.
SUMMARY: The Food and Drug Administration (FDA) is announcing the Web site location where it will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development. In addition, FDA has established a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidance documents.

DATES: Submit either written or electronic comments at any time.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify comments with the docket number found in brackets in the heading of this document.


SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of guidance documents that CDRH is considering for development and providing stakeholders an opportunity to provide comments and/or draft language for those topics, or suggestions for new or different guidance documents. This notice announces the Web site location of the list of guidance documents on which CDRH has already issued level 1 guidance documents that indicate the relative priority of different guidance topics to interested stakeholders.

Through feedback from stakeholders, including draft language for guidance documents, CDRH expects to be able to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. This list will be the fourth annual list CDRH has posted. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the list. FDA has established a docket where comments about the FY 2011 list, draft language for guidance documents on those topics, and suggestions for new or different guidance documents may be submitted (see ADDRESSES). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual agency-wide notice issued by FDA under its good guidance practices. This CDRH list, however, will be focused exclusively on device-related guidances and will be made available on FDA’s Web site prior to the beginning of each FY from 2008 to 2012.

To access the list of the guidance documents CDRH is considering for development in FY 2011, visit the FDA Web site http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is not 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.


Nancy K. Stade, Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–24669 Filed 9–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention

Board of Scientific Counselors (BSC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC and NCEH/ATSDR announces the following committee meeting:

TIMES AND DATES: 8:30 a.m.–4:15 p.m., October 21, 2010. 8:30 a.m.–12 p.m., October 22, 2010.

PLACE: CDC, 4770 Buford Highway, Atlanta, Georgia 30341.

STATUS: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

PURPOSE: The Secretary, Department of Health and Human Services (HHS) and by delegation, the Director, CDC and Administrator, NCEH/ATSDR, are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to: (1) Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist States and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and well being; and (3) train State and local personnel in health work. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agency’s...