guidance is in the form of an annex to the core ICH Q4B guidance made available in the **Federal Register** of February 21, 2008 (73 FR 9575). Once finalized, the annex will provide guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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. 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.

III. Electronic Access

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

Dated: July 9, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–17485 Filed 7–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Child Health and Human Development Special Emphasis Panel, July 16, 2010, 10 a.m. to July 16, 2010, 12 p.m., National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on June 28, 2010, 75 FR 36662.

The date of the meeting has been changed from July 16, 2010 to August 9, 2010. The meeting is closed to the public.

Dated: *July 12, 2010.*

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–17567 Filed 7–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Surveillance, Natural History, Quality of Care and Outcomes of Diabetes Mellitus With Onset in Childhood and Adolescence, RFA DP 10–001, Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 1 p.m.–2:30 p.m., August 3, 2010 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of "Surveillance, Natural History, Quality of Care and Outcomes of Diabetes Mellitus with Onset in Childhood and Adolescence, RFA DP 10–001."

Contact Person for More Information: Donald Blackman, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K–92, Atlanta, GA 30341, Telephone: (770) 488–3023, E-mail: *DBY7@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 13, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–17562 Filed 7–16–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, the Department of Health and Human Services is hereby giving notice that the Advisory Commission on Childhood Vaccines (ACCV) will hold a special meeting, to be held by teleconference. This meeting will be equivalent to an in-person meeting and will be open to the public.

Date and Time: The ACCV will meet on Thursday, July 29 from 1 p.m. to 2 p.m. (ET). The public can join the meeting via audio conference call by dialing 1–888–606–5950 on July 29 at 1 pm and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: This is a special meeting of the ACCV. Discussions will surround the draft interim influenza vaccine information materials developed by the Centers for Disease Control and Prevention (CDC) for distribution during the 2010–2011 season by health care providers in the United States to all seasonal influenza vaccine recipients (or to parents or legal representatives in certain cases). For this special meeting, members of the public are invited to attend by teleconference via a toll-free call-in phone number.

SUPPLEMENTARY INFORMATION: Section 2126 of the Public Health Service Act, as amended, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any person (or to parents or legal representatives in certain cases) receiving vaccines covered under the VICP.

Development and revision of vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the CDC. Section 2126 requires that the

materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the ACCV, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

(1) A concise description of the benefits of the vaccine,

(2) A concise description of the risks associated with the vaccine,

(3) A statement of the availability of the National Vaccine Injury Compensation Program, and

(4) Such other relevant information as may be determined by the Secretary.

Instructions for use of the vaccine information materials and copies of the materials can be found on the CDC Web site at: *http://www.cdc.gov/vaccines/pubs/VIS/.* In addition, single camera-ready copies may be available from State health departments.

The meeting described in this notice fulfills the legal requirements that the ACCV be consulted concerning the development or revision of vaccine information materials with respect to vaccines covered under the National Vaccine Injury Compensation Program.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail: *aherzog@hrsa.gov.* Requests should contain the name, address, telephone number, e-mail address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by e-mail, mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

This meeting notice is being published less than the normally required 15-day timeframe due to the public health urgency of this agency business and in order to assure that completed vaccine information materials will be available for distribution prior to the beginning of vaccination for the upcoming influenza season (41 CFR 102–3.150(b)).

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the ACCV should contact Annie Herzog, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–6593 or e-mail: *aherzog@hrsa.gov.*

Dated: July 12, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–17437 Filed 7–14–10; 4:15 pm]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Human Therapeutics for the Treatment of Cancer

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

ACTION: Notice.

SUMMARY: This is a notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in US Patent Application 61/241,620 entitled "Development of an Immunotoxin in Which All B–Cell Epitopes Have Been Removed and Which Has High Cytotoxic Activity" [HHS Ref. E–269–2009/0–US–01], US Patent Application 60/969,929 entitled "Deletions in Domain II of Pseudomonas Exotoxin A That Reduce Non-Specific Toxicity" [HHS Ref. E–292–2007/0–US–01], US Patent Application 60/703,798 entitled "Mutated Pseudomonas Exotoxins with Reduced Antigenicity" [HHS Ref. E–262–2005/0–US–01], and all continuing applications and foreign counterparts, to MedImmune, LLC. This license may also include non-exclusive rights to US Patent Application 60/525,371 entitled "Mutated Anti-CD22 Antibodies and Immunoconjugates" [HHS Ref. E–046–2004/0–US–01], US Patent Application 60/325,360 entitled "Mutated Anti-CD22 Antibodies with Increased Affinity to CD22 Expressing Leukemia Cells" [HHS Ref. E–129–2001/0–US–01], US Patent Application 60/041,437 entitled "Recombinant Immunotoxins Targeted to CD22 Bearing Cells and Tumors" [HHS Ref. E–059–1997/0–US–01], US Patent 5,747,654 entitled "Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity" [HHS Ref. E–163–1993/0–US–01], PCT application PCT/US96/16327 entitled "Immunotoxin Containing A Disulfide-Stabilized Antibody Fragment" [HHS Ref. E–163–1993/2–PCT–01], and all continuing applications and foreign counterparts. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

The use of the HA22–LR, HA22–6X, HA22–8X, HA22–LR/6X and HA22–LR/8X immunotoxins for the treatment of CD22-expressing hematological malignancies.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 3, 2010 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4632; Facsimile: (301) 402–0220; E-mail: *lambertsond@od.nih.gov.*

SUPPLEMENTARY INFORMATION: These inventions concern immunotoxins and methods of using the immunotoxins for the treatment of hematological malignancies such as hairy cell leukemia (HCL), chronic lymphocytic leukemia (CLL), acute lymphocytic leukemia (ALL) and non-Hodgkin's lymphoma (NHL). Several specific immunotoxins are covered by this technology, including HA22–LR, HA22–6X, HA22–8X, HA22–LR/6X and HA22–LR/8X.

Each of these immunotoxins comprises (1) a toxin moiety that is a modified version of the *Pseudomonas* exotoxin A ("PE") and (2) an antibody fragment domain that is capable of binding to the CD22 cell surface receptor. The PE moieties have been modified in various manners in order reduce the immunogenicity of the molecule. The modifications improve the therapeutic value of PE while maintaining its ability to trigger cell death. Since CD22 is preferentially expressed on several types of hematological cancer cells, the anti-CD22 antibody binding fragment allows the immunotoxins to be targeted