

Dated: March 6, 2007.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Immune Globulins for Primary Immune Deficiency Diseases: Antibody Specificity, Potency and Testing; 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: Immune Globulins for Primary Immune Deficiency Diseases: Antibody Specificity, Potency and Testing. The purpose of the public workshop is to discuss approaches to identify the most relevant antibody specificities in Immune Globulins for the prevention of infections in patients with primary immune deficiency diseases (PIDD), and current and potential potency tests for Immune Globulins. The public workshop will also include a discussion about the declining measles antibody levels in U.S. licensed Immune Globulins and the potential clinical impact on patients with PIDD. The public workshop sponsors are FDA, the Immune Deficiency Foundation, and the Plasma Protein Therapeutics Association.

Date and Time: The public workshop will be held on April 25, 2007, from 8 a.m. to 5 p.m., and April 26, 2007, from 8:30 a.m. to 11:30 a.m.

Location: The public workshop will be held at the Lister Hill Center Auditorium, Building 38A, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: rhonda.dawson@fda.hhs.gov.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by April 6, 2007. 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 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The public workshop will feature presentations by national and international experts from government, academic institutions, and industry. The first day of the workshop will include discussions on: (1) Epidemiology of serious infections in PIDD patients; (2) review of European and U.S. PIDD registry data; (3) surveillance questions to address the type, rate, and severity of infections in PIDD patients; (4) rationale for current potency tests for Immune Globulins; (5) antibody levels in current Immune Globulins, including those levels to emerging pathogens; and (6) the development of additional or other useful potency tests. The second day of the workshop will focus on the potential clinical impact on PIDD patients of declining measles antibody levels in U.S. licensed Immune Globulins.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: March 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers, and Practitioners (OMB No. 0915-0239)—Extension

Section 221 (a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 specifically directs the Secretary to establish a national health care fraud and abuse data collection program for the reporting and disclosure of certain final adverse actions taken against health care providers, suppliers, and practitioners. A final rule was published October 26, 1999, in the **Federal Register** to implement the statutory requirements of section 1128E of the Social Security Act (The Act) as added by section 221 (a) of HIPAA. The Act requires the Secretary to implement the national health care fraud and abuse data collection program. This data bank is known as the Healthcare Integrity and Protection Data Bank (HIPDB). It contains the following types of information: (1) Civil judgments against a health care provider, supplier, or practitioner in Federal or State court related to the delivery of a health care item or service; (2) Federal or State criminal convictions against a health care provider, supplier, or practitioner related to the delivery of a health care item or service; (3) actions by Federal or State agencies responsible for the licensing and certification of health care providers, suppliers, or practitioners; (4) exclusion of a health care provider, practitioner or supplier from participation in Federal or State health care programs; and (5) any other adjudicated actions or decisions that the Secretary shall establish by regulations. Access to this data bank is limited to