

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

Federal and State Government agencies and health plans.

The reporting forms and the request for information forms (query forms) must be accessed, completed, and

submitted to the HIPDB electronically through the HIPDB Web site at <http://www.npdb-hipdb.hrsa.gov>. All reporting and querying is performed through this secure Web site. Due to overlap in

requirements for the HIPDB, some of the National Practitioner Data Bank's burden has been subsumed under the HIPDB.

Estimates of burden are as follows:

Regulation citation	Number of respondents	Frequency of responses	Hours per response (min.)	Total burden hours
61.6(a), (b) Errors & Omissions	172	4.3	15	184.9
61.6 Revisions/Appeal Status	107	23.25	30	1,243.9
61.7 Reporting by State Licensure Boards	275	70.3	45	14,499.4
61.8 Reporting of State Criminal Convictions	62	8	45	372
61.9 Reporting of Civil Judgments	54	13	45	526.5
61.10(b) Reporting Exclusions from participating in Federal and State Health Care Programs	10	441.4	45	3,310.5
61.11 Reporting of adjudicated actions/decisions	410	12.5	45	3,843.8
61.12 Request for Information—State Licensure Boards	1,000	67.5	5	5,622.8
61.12 Request for Information—State Certification Agencies	16	6	5	8
61.12 Request for Information States/District Attorneys & Law Enforcement	2,000	25	5	4,165
61.12 Request for Information—State Medicaid Fraud Units	47	50	5	195.8
61.12 Request for Information—Health Plans	2,841	263.8	5	62,429.7
61.12 Request for Information—Health Care Providers, Suppliers, Practitioners (Self-query)	37,925	1	25	15,799.6
61.12(a)(4) Request by Researchers for Aggregate Data	1	1	30	.5
61.15 Place Report in Dispute	459	1	5	38.2
61.15 Add a Subject Statement	238	1	45	178.5
61.15 Request for Secretarial Review	43	1	480	344
Entity Registration	2,500	1	60	2,500
Entity Registration—Update	451	1	5	37.6
Entity Reactivation	450	1	60	450
Authorized Agent Designation	100	1	15	25
Authorized Agent Designation—Update	250	1	5	20.8
Account Discrepancy	1,000	1	15	250
Electronic Funds Transfer Authorization	400	1	15	100
Total				116,146.5

Numbers in the table may not add up exactly due to rounding.

Send comments to Susan G. Queen, PhD, HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 5, 2007.

Alexandra Huttinger,
Acting Director, Division of Policy Review and Development.

[FR Doc. E7–4411 Filed 3–9–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

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Proposed Project: The Organ Procurement and Transplantation Network (OMB No. 0915–0286)—Extension

The Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. OMB requires review and approval of recordkeeping and reporting requirements associated with the final rule governing the operation of the OPTN (42 CFR Part 121) related to Secretarial review and appeals. There are recordkeeping and reporting requirements associated with the process for filing appeals in the case where applicants are rejected for membership or designation in the OPTN. To date, no appeals have been filed. The burden requirements for this process are minimal. The estimate of burden for this process consists of preparing a letter requesting reconsideration and compiling supporting documentation.