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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Intravenous Immune Globulins in the 21st Century: Progress and Challenges in Efficacy, Safety, and Paths to Licensure; 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: "Intravenous Immune Globulins in the 21st Century: Progress and Challenges in Efficacy, Safety, and Paths to Licensure." The purpose of the workshop is to address current topics on the safety and efficacy of immune globulin products.

Date and Time: The workshop will be held on April 13, 2005, from 8 a.m. to 5:30 p.m.

Location: The workshop will be held at the Lister Hill Auditorium, Bldg. 38A, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3514, FAX: 301-827-2843, e-mail: dawsonr@cber.fda.gov.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by April 1, 2005. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration. Registration on the day

of the public workshop will be provided on a space available basis beginning at 7:15 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, in cooperation with the Primary Immune Deficiency Foundation, is announcing the following public workshop:

“Intravenous Immune Globulins in the 21st Century: Progress and Challenges in Efficacy, Safety, and Paths to Licensure.” The 1-day workshop, consisting of three successive sessions, will discuss the following topics:

- Specific antibody levels in intravenous immune globulins (IGIVs) to common and emerging pathogens, including research questions concerning antibody levels and efficacy;
- Adverse events, including specific categories of adverse events, as well as current methods of surveillance, responses to adverse event information, and the utility of different monitoring strategies; and
- Paradigms for IGIV and subcutaneous immune globulin licensure for treatment of Primary Immune Deficiency.

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, 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: 3/3/05
March 3, 2005.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

John

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