evaluation of these drugs to WHO, through the Secretary of State, for WHO’s consideration in deciding whether to recommend international control/decontrol of any of these drugs. Such control could limit, among other things, the manufacture and distribution (import/export) of these drugs and could impose certain recordkeeping requirements on them.

HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in early 2015. Any HHS position regarding international control of these drugs will be preceded by another Federal Register notice soliciting public comments, as required by section 201(d)(2)(B) of the CSA.

IV. Comments

Interested persons may submit either electronic comments regarding the drugs to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES) by January 29, 2014. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this notice. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: December 24, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Strategies To Address Hemolytic Complications of Immune Globulin Infusions; 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 “Strategies to Address Hemolytic Complications of Immune Globulin Infusions.” The purpose of the public workshop is to identify and discuss potential risk mitigation strategies for Immune Globulin (Ig)-associated hemolysis and to identify and discuss important research questions related to patient risk and product characteristics. The workshop has been planned in partnership with the National Heart, Lung, and Blood Institute, National Institutes of Health, and the Plasma Protein Therapeutics Association. The workshop will include presentations and panel discussions by experts from academic institutions, industry, and government agencies.

Dates and Times: The public workshop will be held on January 28, 2014, 8:30 a.m. to 5 p.m. and January 29, 2014, 8:30 a.m. to 12 noon. Location: The public workshop will be held at Lister Hill Center Auditorium, National Institutes of Health Campus, Building 38A, 8600 Rockville Pike, Bethesda, MD 20894.


Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Chris Nguyen (see Contact Person) at least 7 days in advance, and will be posted to the docket at http://www.regulations.gov.


Leslie Kux,
Assistant Commissioner for Policy.

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