the Collection of Platelets, Pheresis.'' In addition, in recent years, many improvements have been made in automated blood cell separator technology and blood cell counting methods. Automated blood cell separator devices are now capable of various plateletpheresis collection procedures including, but not limited to, collection of double and triple platelet components obtained during a single procedure; use of in-process leukocyte reduction; collection of concurrent plasma components; and collection of concurrent Red Blood Cell components. When finalized, the draft guidance will replace the October 1988 guideline.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic.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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance are under FDA's regulations at parts 211, 601, 606, 610, and 640 (21 CFR parts 211, 601, 606, 610, and 640). Part 211, subpart J (Records and Reports) was approved under OMB control number 0910–0139; part 606, subpart I (Records and Reports) was approved under OMB control numbers 0910–0116 and 0910–0458. Sections 606.100(b) and (c), 606.110(a), 606.121, 606.122, 640.25, and 640.27 were approved under OMB control number 0910–0116; §§ 211.22, 211.80, 211.100(b), and 211.160 were approved under OMB control number 0910–0139; § 610.2 was approved under OMB control number 0910–0206; and §§ 601.12 and 610.60 were approved under OMB Control No. 0910–0338.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19727 Filed 9–30–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0390]

International Conference on Harmonisation; Draft Guidance on E2B(R) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E2B(R) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance, which revises previous guidance on the same topic, provides standardized data elements for the transmission of individual case safety reports for preapproval and postapproval reporting periods. The revisions in this draft guidance include additional information and clarifications for the electronic transmission of individual case safety reports. The draft guidance is intended to be used with other ICH recommendations for electronic transmissions.

DATES: Submit written or electronic comments on the draft guidance by October 28, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research (CBER) Voice Information System at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Roger Goetsch, Center for Drug Evaluation and Research (HFD–410), Food and Drug Administration, 12300 Twinbrook Pkwy., Rockville, MD 20851, 301–770–9299, or Lise Stevens-Hawkins, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6085.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical

requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

The ICH guidance entitled ''E2B Data Elements for Transmission of Individual Case Safety Reports'' was signed off by ICH in July 1997 and issued by FDA in January 1998 (63 FR 2396, January 15, 1998). ICH subsequently issued a revised guidance entitled ''E2B(M) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports'' (E2B(M)), to provide additional information and clarification. ICH signed off on E2B(M) in November 2001, and FDA issued the revised guidance in April 2002.

In May 2005, the ICH Steering Committee agreed that the E2B(M) draft guidance should be made available for public comment. The draft guidance is the product of the E2B(R) Expert Working Group of the ICH. Comments about the draft guidance will be considered by FDA and the E2B(R) Expert Working Group.

FDA is announcing the availability of the draft guidance entitled ''E2B(R) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports,'' which revises the previous E2B guidances to include additional information and clarification for the electronic transmission of individual case safety reports. The draft guidance incorporates adjustments based on experience gained after implementation of the guidance in the three ICH regions and expands the use of the standard data elements to support vaccine reporting. For electronic transmissions, the draft guidance is intended to be used with the ICH M2 individual case safety report (ICSR) message specification. The draft guidance recommends that electronic transmission of individual case safety reports be implemented using the Medical Dictionary for Regulatory Activities (MedDRA) and ICH M5 data elements and standards where applicable.

FDA has identified in public Docket No. 1992S–0251 (formerly Docket No. 92S–0251) postmarketing individual case safety reports as submission types that the agency can accept in electronic format. FDA believes the ICH recommendations for the electronic transmission of these reports will result in more effective and efficient safety reporting to regulatory authorities worldwide.

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**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and 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.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: September 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19655 Filed 9–30–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Waiver of Compliance With Navigation and Inspection Laws; Gulf Coast States

AGENCY: Office of the Secretary, DHS.

ACTION: Notice.

The combined effect of Hurricanes Rita and Katrina is one of the largest natural disasters to ever strike the United States. The hurricanes have significantly disrupted production of oil and gas in the Gulf of Mexico, have caused many Gulf Coast oil refineries to go out of service because of flooding, lack of electric power or other reasons, and have significantly disrupted the pipeline transportation of oil and refined products from the Gulf Coast States. These production losses, outages, and disruptions have caused increases in the price of oil, gasoline and other refined products. The Department of Homeland Security has received reports of threatened or actual shortages of gasoline, jet fuel, and/or other refined products as a result of the hurricanes.

Companies that produce and/or ship petroleum and/or refined petroleum products have submitted to the Department requests for waivers of the Merchant Marine Act of 1920 (the ''Jones Act''). See, 46 U.S.C. App. section 1; 46 U.S.C. App. section 883. This and related laws are generally referred to as the ''coastwise laws.'' These laws provide, among other things, that only vessels built and owned by citizens of the United States and flagged in the United States can carry merchandise between U.S. ports.

The Secretary of Homeland Security is vested with the authority and discretion to waive the coastwise laws ''to such extent and in such manner and upon such terms as he may prescribe, either upon his own initiative or upon the written recommendation of the head of any other Government agency, whenever he deems that such action is necessary in the interest of national defense.'' In consultation with and upon the recommendation of the Secretary of Energy, I have determined that such a waiver, in accordance with the terms set forth below, is in the interest of the national defense.