FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cathy Miller at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 7, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15834 Filed 8–13–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0307] (Formerly Docket No. 98D–0307)

Guidance for Industry on Exports Under the Food and Drug Administration Export Reform and Enhancement Act of 1996; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''FDA Guidance for Industry: Exports Under the FDA Export Reform and Enhancement Act of 1996.'' The guidance document addresses issues pertaining to the exportation of human drugs, animal drugs, biologics, devices, food, food additives, color additives and dietary supplements under the FDA Export Reform and Enhancement Act.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Include a self-addressed adhesive label to assist that office in processing your request. Submit written comments 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*.

FOR FURTHER INFORMATION CONTACT: Barbara Ward-Groves, Office of International Programs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480 or 404–253–1221.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 12, 1998 (63 FR 32219), FDA published a draft guidance document entitled ''FDA Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996.'' FDA wrote the draft guidance to help interested parties understand and comply with the FDA Export Reform and Enhancement Act. Enacted and later amended in 1996, the FDA Export Reform and Enhancement Act (Public Law 104–134, as amended by Public Law 104–180) significantly changed the export requirements for human drugs, animal drugs, biologics, devices, and, to a limited extent, food additives. For example, before the law was enacted, most exports of unapproved new drug products could only be made to 21 countries identified in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382), and these exports were subject to various restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA). (Currently, the EU countries are Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Currently, the EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA.)

The guidance document provides information on the statutory and regulatory requirements for exporting FDA-regulated products, including general requirements for products exported under section 801 of the act, labeling requirements for drugs and biologics exported under section 801(e) of the act, export requirements for unapproved drugs, biologics, and devices under section 802(b) of the act, exports of unapproved drugs and devices for investigational use, exports of unapproved drugs and devices in anticipation of foreign approval, exports of drugs and devices for diagnosing, preventing, or treating a tropical disease or disease ''not of significant prevalence in the United States,'' and export notifications to FDA. The guidance document announced in this notice finalizes the draft guidance issued June 12, 1998.

The guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115) and represents FDA's current thinking on exports under sections 801(e) and 802 of the act. 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 regarding this document. 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 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

An electronic version of the guidance is available on the Internet at *http://www.fda.gov* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 7, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

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