

publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug

was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person

petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug. FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 016908 .....	LIDEX (fluocinonide) Cream; Topical, 0.05%, .....	Medicis Pharmaceutical Corp., 7720 North Dobson Rd., Scottsdale, AZ 85256.
Do. ....	LIDEX-E (fluocinonide) Cream; Topical, 0.05% .....	Do.
NDA 018181 .....	MYCELEX (clotrimazole) Solution; Topical, 1% .....	Bayer Health Care, 100 Bayer Rd., Pittsburgh, PA 15205.
NDA 018713 .....	MYCELEX (clotrimazole) Lozenge; Oral, 10 milligrams (mg)	Do.
NDA 019510 .....	PEPCID (famotidine) Injection, 10 mg/milliliter (mL) .....	Merck Research Laboratories, Inc., 770 Sumneytown Pike, West Point, PA 19486.
Do. ....	PEPCID PRESERVATIVE FREE (famotidine) Injection, 10 mg/mL.	Do.
NDA 020249 .....	PEPCID PRESERVATIVE FREE IN PLASTIC CONTAINER (famotidine) Injection, 0.4 mg/mL.	Do.
NDA 021065 .....	FEMHRT (ethinyl estradiol; norethindrone acetate) Tablet; Oral, 0.005 mg/1 mg.	Warner Chilcott LLC, 1 Grand Canal Sq., Docklands, Dublin 2, Ireland.
NDA 050763 .....	MITOZYTREX (mitomycin) Injection, 5 mg/vial .....	SuperGen, Inc., 4140 Dublin Blvd., Suite 200, Dublin, CA 94568.
ANDA 086031 .....	ISOSORBIDE DINITRATE (isosorbide dinitrate) Tablet; Sublingual, 5 mg.	Watson Laboratories, 577 Chipeta Way, Salt Lake City, UT 84108.
ANDA 086033 .....	ISOSORBIDE DINITRATE (isosorbide dinitrate) Tablet; Sublingual, 2.5 mg.	Do.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 13, 2013.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
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**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2000-D-0187 (formerly Docket No. 2000D-1267)]

**Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry, and Product Management To Reduce the Risk of Transfusion-Transmitted Malaria; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria" dated August 2013. The guidance document provides blood

establishments that collect blood and blood components with recommendations for questioning and deferring donors of blood and blood components, allowing their reentry, and product management to reduce the risk of transfusion-transmitted malaria. This guidance finalizes the draft guidance of the same title dated June 2012, and supersedes the FDA memorandum to all registered blood establishments entitled "Recommendations for Deferral of Donors for Malaria Risk" dated July 26, 1994. The recommendations contained in the guidance are not applicable to donors of Source Plasma.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for

electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Melissa Reisman, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance document entitled "Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria" dated August 2013. The guidance document provides blood establishments that collect blood and blood components with recommendations for questioning and deferring donors of blood and blood components, and allowing their reentry, to reduce the risk of transfusion-transmitted malaria. This guidance document also provides recommendations for product management, including recommendations regarding product retrieval and quarantine, and notification of consignees of blood and blood components in the event that a blood establishment determines that blood or blood components have been collected from a donor who should have been deferred due to possible malaria risk. Finally, the guidance contains recommendations on the implementation of FDA's recommendations, including how licensed blood establishments must report to FDA the changes made to their donor history questionnaires to reflect the new donor deferral recommendations.

In the **Federal Register** of July 6, 2012 (77 FR 40068), FDA announced the availability of the draft guidance of the same title dated June 2012. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Significant changes to the guidance include: revisions to the definition of malaria-endemic area, malaria-endemic country and other terms used to assess a donor's risk of malaria based on history of travel or residence; and revisions to the

recommendations regarding consignee notification and reporting of biological product deviations for acellular blood components collected from a donor at risk for malaria. Based on the revised definition of malaria-endemic area and current epidemiological data, donors who travel to the Mexican States of Quintana Roo or Jalisco would be eligible for donation without any deferral, provided the donors meet all other eligibility criteria. However, if malaria transmission in these States changes over time, the donor deferral recommendations would encompass donors who travel to these areas. The guidance announced in this notice finalizes the draft guidance dated June 2012, and supersedes the FDA memorandum to all registered blood establishments entitled "Recommendations for Deferral of Donors for Malaria Risk," dated July 26, 1994.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 requirements of the applicable statutes and regulations.

**II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 21 CFR part 640 and 21 CFR 630.6 have been approved under OMB control number 0910-0116. The collections of information in 21 CFR 606.171 have been approved under OMB control number 0910-0458.

**III. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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>.

**IV. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 13, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2013-M-0462, FDA-2013-M-0463, FDA-2013-M-0464, FDA-2013-M-0549, FDA-2013-M-0592, FDA-2013-M-0594, FDA-2013-M-0595, FDA-2013-M-0709, FDA-2013-M-0724, FDA-2013-M-0738, and FDA-2013-M-0758]

**Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

**FOR FURTHER INFORMATION CONTACT:** Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C.