

estimates for this request. The availability of the form, and the opportunity to provide the information in electronic format, could reduce this estimate. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of the form and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a GRAS notification.

Dated: January 11, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-783 Filed 1-17-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-P-0756]

#### Determination That PREZISTA (darunavir) Tablets, 300 Milligrams Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that PREZISTA (darunavir) Tablets, 300 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for darunavir tablets, 300 mg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6320, Silver Spring, MD 20993-0002, (301) 796-3472.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to

gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PREZISTA (darunavir) Tablets, 300 mg, is the subject of NDA 21-976, held by Tibotec, Inc., and initially approved on June 23, 2006. PREZISTA is a human immunodeficiency virus (HIV-1) protease inhibitor indicated for the treatment of HIV-1 infection in adult patients. PREZISTA is also indicated for the treatment of HIV-1 infection in pediatric patients 6 years of age and older. PREZISTA must be coadministered with ritonavir (PREZISTA/ritonavir) and with other antiretroviral agents.

PREZISTA (darunavir) Tablets, 300 mg, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Lupin Pharmaceuticals, Inc. (Lupin), submitted a citizen petition dated October 14, 2011 (Docket No. FDA-2011-P-0756), under 21 CFR 10.30, requesting that the Agency determine whether PREZISTA (darunavir) Tablets, 300 mg, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PREZISTA (darunavir) Tablets, 300 mg, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner Lupin has identified no data or other information suggesting that PREZISTA

(darunavir) Tablets, 300 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PREZISTA (darunavir) Tablets, 300 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PREZISTA (darunavir) Tablets, 300 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PREZISTA (darunavir) Tablets, 300 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 11, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-847 Filed 1-17-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2007-D-0020 (formerly Docket No. 2007D-0249)]

#### Guidance for Industry: Preparation of Investigational Device Exemptions and Investigational New Drug Applications for Products Intended To Repair or Replace Knee Cartilage; 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: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage” dated December 2011. The guidance document provides sponsors of an investigational device exemption application (IDE) or an investigational new drug application (IND) recommendations about certain information that should be included in

a submission describing a product intended to repair or replace knee cartilage. The guidance does not apply to prostheses such as unicondylar or total knee implants, or meniscus replacement products. The guidance supplements recommendations regarding IDE and IND submissions contained in other FDA publications. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2007.

**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; or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993. 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; or by calling CDRH at 1-(800) 638-2041 or by faxing a request to CDRH at (301) 847-8149. 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:** Lori Jo Churchyard, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, (301) 827-6210; or Elizabeth L. Frank, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1407, Silver Spring, MD 20993, (301) 796-5650.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a document entitled "Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage" dated December 2011. The guidance document provides sponsors of an IDE

or an IND recommendations about certain information that should be included in a submission describing a product intended to repair or replace knee cartilage. The guidance does not apply to prostheses such as unicondylar or total knee implants, or meniscus replacement products. Human cells, tissues, and cellular and tissue-based products (HCT/P's) regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and 21 CFR part 1271 are beyond the scope of this guidance. A product intended to repair or replace knee cartilage may include a biologic, device, or combination product (comprised of two or more different types of regulated constituents) whose components would individually be regulated by CBER and CDRH. The guidance addresses issues that may arise in the development of articular cartilage repair or replacement products. The guidance supplements other FDA publications on IDEs and INDs that may be relevant to development of these products.

In the **Federal Register** of July 9, 2007 (72 FR 37245), FDA announced the availability of the draft guidance of the same title dated July 2007. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. In response to comments, changes incorporated in the guidance included adding new sections and clinical study schedules, elaborating on nonclinical data considerations, and updating the references. In addition, organizational and editorial changes were made to improve clarity. Some terminology was changed to harmonize terminology within the Agency and does not change the intent of the guidance. The guidance also reflects input received from the public and the Cellular, Tissue, and Gene Therapy Advisory Committee meeting held on May 15, 2009. The guidance announced in this notice finalizes the draft guidance dated July 2007.

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**

The 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 312 have been approved under OMB control number 0910-0014; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078.

##### **III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

##### **IV. Electronic Access**

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

Dated: January 11, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2011-N-0002]

#### **Ethical and Regulatory Challenges in the Development of Pediatric Medical Countermeasures; Public Workshop**

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA), Office of Pediatric Therapeutics, is announcing a public workshop entitled "Ethical and Regulatory Challenges in the Development of Pediatric Medical Countermeasures." There is a critical need for pediatric research on medical countermeasures to ensure that these products are safe and effective in the pediatric population. The challenges to developing and evaluating drugs, biologics, and devices for children in the medical countermeasure context are complex