DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 2 2014

Joan Janulis, R.A.C.
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Re: Docket No. FDA-2013-P-1379

Dear Ms. Janulis:

This letter responds to your citizen petition received on October 22, 2013, requesting that the Food and Drug Administration (FDA) determine whether PREZISTA (darunavir) tablets, 400 mg, was withdrawn from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and determined that PREZISTA (darunavir) tablets, 400 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain PREZISTA (darunavir) tablets, 400 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-3990.

Sincerely,

Na'Im R. Moses
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

development efforts provide tailored resource support to *Senior Legal Helplines* (SLH) and *Model Approaches to Statewide Legal Assistance Systems* (Model Approaches) projects across the country. Model Approaches grants promote the creation of legal services delivery systems that incorporate SLHs (and other low-cost service delivery mechanisms) into the broader tapestry of Title III–B legal services, and other available legal resources. Specifically, the TA grant directed to SLHs provides resource support for various aspects of helpline legal service delivery, including the development of reporting/data collection systems, case management systems, targeting and outreach strategies, and integration strategies that incorporate SLHs into the broader tapestry of legal service delivery in each Model Approaches state. The TA grant directed to the systems enhancement objectives of Model Approaches Phase I and Phase II projects provides resource support on the development of needs and capacity assessments, reporting/data collection systems and outcomes measures used to determine the impact of legal services, and the development of legal service delivery standards/guidelines that promote quality and consistent statewide legal service delivery.

II. Justification for The Exception to Competition

As with the grants comprising the National Legal Resource Center, it is important to assess the effectiveness of TA grants in helping states meet increasing challenges in the development and maintenance of "high capacity" statewide legal service delivery systems. To this end, ACL would like to accomplish two goals this year: (1) Obtain stakeholder input on the resource support needs of legal and aging/disability service providers across the country and the ability to meet those needs through focused TA grants; and (2) establish how best to direct the current objectives of the TA grants towards advancing anticipated ACL FY 15 activities related to elder rights and elder abuse prevention.

III. Eligible Applicants

Incumbent TA grantees with award expiration dates of 5/31/14.

IV. Evaluation Criteria

Information previously provided in semi-annual reports, as well as information in the non-competing extension application will be considered to determine satisfactory progress of the grantee project and ensure that proposed activities are within the approved scope and budget of the grant. Areas that will be evaluated include:

A. *Project Relevance & Current Need*
B. *Approach*
C. *Budget*
D. *Project Impact*
E. *Organizational Capacity*

V. Application and Submission Requirements

A. SF 424—Application for Federal Assistance
B. SF 424A—Budget Information
C. Separate Budget Narrative/Justification
D. SF 424B—Assurances. Note: Be sure to complete this form according to instructions and have it signed and dated by the authorized representative (see item 18d of the SF 424).
E. Lobbying Certification
F. Program narrative—no more than 10 pages.
G. Work Plan
H. Incumbent grantees will be required to access the non-competing application kit in GrantSolutions.gov to submit all materials for this application.

VI. Application Review Information

Applications will be objectively reviewed by Federal staff utilizing the criteria listed above in Section III.

VII. Agency Contact

For further information or comments regarding this program expansion supplement, contact Omar Valverde, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging, Office of Elder Rights, One Massachusetts Avenue NW., Washington, DC 20001; telephone (202) 357–3515; fax (202) 357–3549; email *omar.valverde@acl.hhs.gov.*

Dated: March 27, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2014–07340 Filed 4–1–14; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0796]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Testing Communications on Medical Devices and Radiation-Emitting Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Testing Communications on Medical Devices and Radiation-Emitting Products" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 20, 2013, the Agency submitted a proposed collection of information entitled "Testing Communications on Medical Devices and Radiation-Emitting Products" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0678. The approval expires on March 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07325 Filed 4–1–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–1379]

Determination That PREZISTA (Darunavir) Tablets, 400 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 or the Agency) has determined that PREZISTA (darunavir) tablets, 400 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, 400 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Na'Im R. Moses, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 240–402–3990.

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 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, 400 mg, is the subject of NDA 21–976, held by Janssen Products, LP, 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. It is also indicated for the treatment of HIV–1 infection in pediatric patients 3 years of age and older. PREZISTA must be coadministered with ritonavir (PREZISTA/ritonavir) and with other antiretroviral agents.

In an email dated July 30, 2013, Janssen Products, LP, notified FDA that PREZISTA (darunavir) tablets, 400 mg, was being discontinued for the U.S. market only. The PREZISTA 800-mg tablet continues to be marketed in the United States. Lachman Consultant Services, Inc., submitted a citizen petition dated October 21, 2013 (Docket No. FDA–2013–P–1379), under 21 CFR 10.30, requesting that the Agency determine whether PREZISTA (darunavir) tablets, 400 mg, was withdrawn from sale for reasons of safety or effectiveness. In January 2014, FDA moved the 400-mg dosage strength of this drug product to the "Discontinued Drug Product List" section of the Orange Book.

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, 400 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PREZISTA (darunavir) tablets, 400 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PREZISTA (darunavir) tablets, 400 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PREZISTA (darunavir) tablets, 400 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, 400 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: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07337 Filed 4–1–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0267]

Determination That NIMOTOP (Nimodipine) Capsules, 30 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 or Agency) has determined that NIMOTOP (Nimodipine) Capsules, 30 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of the abbreviated new drug applications (ANDAs) that refer to nimodipine capsules, 30 mg, and it will allow FDA to approve ANDAs that refer to this drug as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Rachel Turow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–5094.

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 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