LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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October 21, 2013

OVERNIGHT COURIER 10/21/13

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20552

CITIZEN PETITION

Dear Sir or Madam:

Lachman Consultant Services, Inc. ("Lachman") is submitting this Citizen Petition in quadruplicate pursuant to 21 § C.F.R. 10.30 and in accordance with the regulations of 21 § C.F.R. 314.161, on behalf of a client, to request that the Commissioner of the Food and Drug Administration determine whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petition requests that the Commissioner of the Food and Drug Administration determine whether PREZISTA® (darunavir) Tablets, 400 mg has been voluntarily withdrawn from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book"). PREZISTA® (darunavir) Tablets, 400 mg, by Janssen, was approved by the FDA on October 21, 2008, under NDA 21-976. Upon approval, PREZISTA® (darunavir) Tablets, 400 mg was considered to be a "listed drug product" by virtue of its listing in the Orange Book. While the electronic Orange Book, accessed on October 18, 2013 (current through September 2013) still lists PREZISTA® Tablets, 400 mg as an actively marketed product, Jansen has publically announced that this dosage strength is being discontinued in favor of the 800 mg dosage strength. (Refer to **Attachment 1**). The petitioner believes that the 400 mg dosage strength has been discontinued from the market place for commercial reasons.

Under FDA regulations, drugs are withdrawn from the market if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 C.F.R. § 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 § C.F.R. 314.161(a)(1)).

As stated above, at the time of this petition's submission, there is no evidence that Janssen is marketing PREZISTA® (darunavir) Tablets, 400 mg. Accordingly, Lachman respectfully requests that FDA determine whether PREZISTA® Tablets, 400 mg was discontinued for reasons of safety or efficacy reasons, in order to enable action on an ANDA referring to PREZISTA® Tablets, 400 mg as the Reference Listed Drug. Should the NDA holder recommence marketing its 400 mg strength of

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PREZISTA® Tablets after the submission of this petition and prior to an FDA response, and there is evidence that the product is available in the marketplace, Lachman will consider this petition moot. Lachman will, at that time, take the appropriate action to request withdrawal of the petition.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which is unfavorable to the petition.

Respectfully submitted,

Joan Janulis, R.A.C.
Vice President

JJ/pk

Attachments: Johnson & Johnson press release, dated 11/9/12, "FDA Approves New 800 mg PREZISTA® (darunavir) Tablet"
Dosing information at www.prezista.com/healthcare/treatmentexperienced/dosing

cc: Martin Shimer (Office of Generic Drugs)

Petition Darunavir 102113

From: (516) 683-1881 Origin ID: RMEA
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