January 22, 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZENS PETITION

Dear Sir or Madam:

Lachman Consultant Services, Inc. hereby submits this petition pursuant to the Federal Food, Drug and Cosmetic Act ("FD&C Act") and in accordance with 21 CFR § 10.25(a) and 10.30 requesting the Commissioner of the Food and Drug Administration to designate a suitable alternative reference standard (RS) for the purpose of conducting *in vivo* bioequivalence studies to support an ANDA application for Prochlorperazine Maleate Tablets USP, 10 mg. Reference is made to the current Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

A. Action Requested

The petitioner respectfully requests the Commissioner of the Food and Drug Administration to designate the approved Prochlorperazine Maleate Tablets USP, 10 mg (A040268) of Jubilant Cadista Pharmaceuticals Inc., as a RS or designate a suitable alternative RS, upon which ANDA applicant can rely for purpose of *in vivo* bioequivalence testing required for ANDA filing.

B. Statement of Grounds

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permits any person to submit to the Food and Drug Administration (FDA or the Agency) an ANDA to seek approval to market a generic drug. In order to obtain approval of an ANDA for a generic drug, an ANDA applicant first must identify the previously approved drug product it seeks to duplicate, i.e., the reference listed drug (RLD), and must show, among other things, that the generic drug is bioequivalent to the RLD. A RS selected by FDA is the specific drug product that the ANDA applicant must use in conducting any in vivo bioequivalence testing required to support approval of its ANDA. All the approved drug products by the FDA are listed in the Orange Book, along with designation of RLD and/or RS.

In accordance with Section III.C.2 of FDA's draft guidance document, ***'Referencing Approved Drug Products in ANDA'***, *"FDA also will consider selecting a new reference standard when the Agency determines that the quantity of the current reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo bioequivalence testing (even if the current reference standard is not in the Discontinued Section of the Orange Book). When selecting a new reference standard, FDA generally selects a drug product that is therapeutically equivalent to the discontinued RLD and is the market leader based on units sold."*

Section III.C.3 of guidance document also states, "*If there is a reference standard in the Active Section of the Orange Book but there are limited or no quantities of the reference standard in distribution, or a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, then the potential applicant may submit a citizen petition under 21 CFR 10.25(a) and 10.30 to request that FDA select that different listed drug also as a reference standard.*"

Currently, the electronic Orange Book identifies COMPAZINE (prochlorperazine maleate) Tablets USP 5 mg and 10 mg (N010571) of Glaxo-Smith-Kline, as RLD; discontinued. (Attachment 1) Moreover, FDA has designated SANDOZ′s product (A040101) as RS. Although not listed as discontinued in Electronic Orange Book, IMS (MAT) data indicates quantity of the current reference standard to be so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for *in vivo* bioequivalence testing.

Table 1 presents excerpt from the Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book) relative to Prochlorperazine Maleate Tablet; Oral listings.

Table 1

Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book) database Current through January 2020*

Market Status	Discontinued	RX	RX	RX
Active Ingredient	PROCHLORPERAZINE MALEATE	PROCHLORPERAZINE MALEATE	PROCHLORPERAZINE MALEATE	PROCHLORPERAZINE MALEATE
Proprietary Name	COMPAZINE	PROCHLORPERAZINE MALEATE	PROCOMP	PROCHLORPERAZINE MALEATE
Application No	N010571	A040101	A040268	A040185
Product Number	002	002	002	001
Dosage Form	TABLET	TABLET	TABLET	TABLET
Route	ORAL	ORAL	ORAL	ORAL
Strength	EQ 10MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	EQ 10MG BASE	EQ 10MG BASE	EQ 10MG BASE
TE Code	-	AB	AB	AB
RLD	No	No	No	No
RS	No	Yes	No	No
Applicant Holder	GLAXOSMITHKLINE	SANDOZ INC	JUBILANT CADISTA PHARMACEUTICALS INC	MYLAN PHARMACEUTICALS INC
Approval Date	Approved Prior to Jan 1, 1982	Jul 19, 1996	Feb 27, 1998	Oct 28, 1996

Approved generic product, Prochlorperazine Maleate Tablets USP, 10 mg (A040268) of Jubilant Cadista Pharmaceuticals Inc., listed in the Orange Book is currently the highest marketed drug product based on IMS data and hence, eligible to be designated as reference standard due to limited or non-availability of the current Orange Book listed RS; Prochlorperazine Maleate Tablets USP, 10 mg (A040101) of SANDOZ INC.

The lack of availability of the current RS is preventing bioequivalence study in support of an Abbreviated New Drug Application. Therefore, the petitioner respectfully requests the Commissioner to designate a marketed, approved generic drug product to be designated as the RS to enable development of a generic version of the subject drug product.

Attachment 1: Current Orange Book Search Results
Attachment 2: Detailed IMS, Moving Annual Total (MAT) data indicating Approved Generic product, Prochlorperazine Maleate Tablets USP, 10 mg (A040268) of Jubilant Cadista Pharmaceuticals Inc., as the U.S market leader.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case but will agree to provide such an analysis if requested by the Agency.

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 petitioner, which are unfavorable to the petition.

Sincerely,

Michelle Ryder

Michelle Ryder
cn=Michelle Ryder, o=Lachman Consultant Services, Inc., ou, email=m.ryder@lachmanconsultants.com, c=US
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Michelle R. Ryder
Principal Consultant
Lachman Consulting Services, Inc.