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

1600 STEWART AVENUE, WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

March 30, 2006

OVERNIGHT COURIER 3/30/06

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

CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Risperdal M Tab (Risperidone) Orally Disintegrating Tablets, 3 mg and 4 mg (NDA No. 21-444), by Janssen Pharma, has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as abbreviated new drug applications in the Approved Drug Product with Therapeutic Equivalence Evaluations ("The Orange Book"). The current electronic edition of the Orange Book includes Risperdal M Tab, 3 mg and 4 mg in the Discontinued Drug Product List section (applicable page attached). A listing in this section of the Orange Book indicates that those drug products designated by the symbol "*" have already been provided with a determination as to whether the drug products were not marketed or withdrawn for safety or efficacy reasons. The listing for Risperdal (Risperidone) Tablets, 3 mg and 4 mg are not designated by the symbol "*". Therefore, it appears that a determination has not been made as to whether the listed drug has been voluntarily withdrawn for safety or effectiveness reasons.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

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As stated, Janssen Pharma's Risperdal (Risperidone) M Tab, 3 mg and 4 mg are not available for sale in the marketplace. Because there is no current commercial distribution of this drug product and because this drug product is listed in the Discontinued Drug Product List section, it is requested that the FDA determine whether Janssen Pharma's decision not to market Risperdal (Risperidone) M Tab, 3 mg and 4 mg was for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 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 petitioner, which is unfavorable to the petition.

Respectfully submitted,

Robert Pollock

Robert W. Pollock
Senior Vice President

RWP/pk

Attachment: Electronic Edition of the Orange Book, Risperdal M Tab, 3 mg and 4 mg in the Discontinued Drug Product List Section

cc: Martin Shimer (Office of Generic Drugs)

R03P6089

LACHMAN CONSULTANT SERVICES, INC.
Westbury, NY 11590

ATTACHMENT

Application Number Search Results from "OB_Disc" table for query on "21444."

Appl No	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
021444	RISPERIDONE	TABLET, ORALLY DISINTEGRATING; ORAL	3MG	RISPERDAL	JANSSEN PHARMA
021444	RISPERIDONE	TABLET, ORALLY DISINTEGRATING; ORAL	4MG	RISPERDAL	JANSSEN PHARMA

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through February, 2006

Patent and Generic Drug Product Data Last Updated: March 29, 2006