

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

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January 16, 2007

OVERNIGHT COURIER 1/16/07

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services (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 of 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Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.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 Seroquel®, 150 mg (quetiapine fumarate) Tablets (NDA 20-639) by AstraZeneca Pharmaceuticals LP, has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.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"). Seroquel® Tablets, 150 mg, were approved by the FDA on December 20, 1998, and were, upon approval, considered to be "listed drug products" and listed in the Orange Book. The 150 mg strength Seroquel® Tablets was the only strength approved on December 20, 1998. FDA has also approved Seroquel® (quetiapine fumarate) Tablets on September 26, 1997 (25 mg, 100 mg, and 200 mg strengths), July 26, 2000 (300 mg strength) and October 4, 2005 (50 mg and 400 mg strengths) under NDA 20-639 that are marketed today. The current listing of the product in the electronic Orange Book, accessed January 12, 2007, does not list the 150 mg strength tablet in the active section of the Orange Book. Rather the 150 mg Seroquel® Tablet is found in the "Discontinued" section of the Orange Book and is currently not available for sale. It is believed the innovator has discontinued the sale of the 150 mg strength of Seroquel® Tablets for commercial reasons.

Under FDA regulations, drugs are withdrawn from market if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162).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 above, at the time of submission of this petition, there is no evidence that AstraZeneca Pharmaceuticals LP is marketing Seroquel® 150 mg. Therefore, because it appears that the product has been discontinued from marketing for commercial purposes, it is requested that the FDA determine whether AstraZeneca's decision to discontinue marketing of their Seroquel® Tablets, 150 mg product was for reasons of safety or effectiveness.

Should the innovator reintroduce this product strength into the market, Lachman Consultant Services, Inc. will consider this petition to be moot and we will take appropriate action to withdraw this petition.

C. Environmental Impact

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

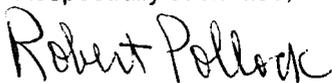
D. Economic Impact

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 W. Pollock *pk*
Senior Vice President
Lachman Consultant Services, Inc.

RWP/pk

Attachment: Electronic Edition of the Orange Book (discontinued and active)

cc: Martin Shimer (Office of Generic Drugs)

T05P7016

Search results from the "OB_Disc" table for query on "020639."

Active Ingredient: QUETIAPINE FUMARATE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: SEROQUEL
Applicant: ASTRAZENECA
Strength: EQ 150MG BASE
Application Number: 020639
Product Number: 004
Approval Date: Dec 20, 1998
RX/OTC/DISCN: DISCN
Patent and Exclusivity Info for this product: [View](#)

[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 December, 2007

Patent and Generic Drug Product Data Last Updated: January 11, 2007

Search results from the "OB_Rx" table for query on "020639."

Active Ingredient: QUETIAPINE FUMARATE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: SEROQUEL
Applicant: ASTRAZENECA
Strength: EQ 25MG BASE
Application Number: 020639
Product Number: 001
Approval Date: Sep 26, 1997
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: QUETIAPINE FUMARATE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: SEROQUEL
Applicant: ASTRAZENECA
Strength: EQ 100MG BASE
Application Number: 020639
Product Number: 002
Approval Date: Sep 26, 1997
Reference Listed Drug: No
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: QUETIAPINE FUMARATE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: SEROQUEL
Applicant: ASTRAZENECA
Strength: EQ 200MG BASE
Application Number: 020639
Product Number: 003
Approval Date: Sep 26, 1997
Reference Listed Drug: No
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: QUETIAPINE FUMARATE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: SEROQUEL
Applicant: ASTRAZENECA
Strength: EQ 300MG BASE
Application Number: 020639

Product Number: 005
Approval Date: Jul 26, 2000
Reference Listed Drug: Yes
RX/OTC/DISCN: RX

TE Code:

Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: QUETIAPINE FUMARATE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: SEROQUEL
Applicant: ASTRAZENECA
Strength: EQ 400MG BASE
Application Number: 020639
Product Number: 006
Approval Date: Oct 4, 2005
Reference Listed Drug: No
RX/OTC/DISCN: RX

TE Code:

Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: QUETIAPINE FUMARATE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: SEROQUEL
Applicant: ASTRAZENECA
Strength: EQ 50MG BASE
Application Number: 020639
Product Number: 007
Approval Date: Oct 4, 2005
Reference Listed Drug: No
RX/OTC/DISCN: RX

TE Code:

Patent and Exclusivity Info for this product: [View](#)

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