LACHMAN CONSULTANT SERVICES, INC.
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January 24, 2006

OVERNIGHT DOCUMENT 1/24/06

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

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate on behalf of a client 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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness for the reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Sustiva® (efavirenz) Tablets, 300 mg (NDA 21-360) manufactured by Bristol Myers Squibb Pharma Company has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.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 that are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the Orange Book, contains all FDA-approved drug products. Sustiva® (efavirenz) Tablets, 300 mg and 600 mg were approved by the FDA on February 1, 2002 and were, upon approval, considered to be "listed drug products" and listed in the Orange Book. It should also be noted that FDA has also approved Sustiva® (efavirenz) Capsules in strengths of 50 mg, 100 mg and 200 mg under NDA 20-972 that are marketed today. The current listing of the product in the electronic Orange Book, accessed January 24, 2006, does not list the 300 mg strength tablet in the active section of the Orange Book, rather the 300 mg Sustiva® Tablet is found in the "Discontinued" section of the Orange Book. It is believed that the innovator has never marketed the 300 mg strength. The FDA has previously determined "for purposes of 21 CFR 314.161 and 314.162 that never marketing an approved product is equivalent to withdrawing the drug from sale." (65 FR 38561)

Under FDA, regulations drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162).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)).

As stated above, at the time of submission of this petition, there is no evidence that the innovator has commenced marketing of its Sustiva® (efavirenz) Tablets, 300 mg. Therefore, because there has been no apparent commercial distribution of this drug product, it is requested that the FDA determine whether the NDA holder's decision not to market Sustiva® (efavirenz) Tablets, 300 mg, was for reasons of safety or effectiveness.

Should the NDA holder commence marketing of Sustiva® (efavirenz) Tablets, 300 mg after the submission of this petition and prior to FDA response and there is evidence that the product is available in the marketplace, LCS will consider the petition moot. We will, at that time, take appropriate action to request withdrawal of the petition.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of 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 to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

E. Certification

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

Respectfully submitted,

Robert Pollock pic

Robert W. Pollock
Vice President

RWP/pk

Attachment: Approved Drug Products with Therapeutic Equivalence Evaluations (Electronic Orange Book), accessed 1/24/06 for Sustiva® (efavirenz) Capsules

cc: M. Shimer (Office of Generic Drugs)

T05P6024

LACHMAN CONSULTANT SERVICES, INC.
Westbury, NY 11590

ATTACHMENT

Search results from the "OB_Rx" table for query on "020972."

Active Ingredient:	EFAVIRENZ
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	SUSTIVA
Applicant:	BRISTOL MYERS SQUIBB
Strength:	50MG
Application Number:	020972
Product Number:	001
Approval Date:	Sep 17, 1998
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Active Ingredient:	EFAVIRENZ
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	SUSTIVA
Applicant:	BRISTOL MYERS SQUIBB
Strength:	100MG
Application Number:	020972
Product Number:	002
Approval Date:	Sep 17, 1998
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Active Ingredient:	EFAVIRENZ
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	SUSTIVA
Applicant:	BRISTOL MYERS SQUIBB
Strength:	200MG
Application Number:	020972
Product Number:	003
Approval Date:	Sep 17, 1998
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

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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, 2005

Patent and Generic Drug Product Data Last Updated: January 24, 2006