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

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December 7, 2001

Dockets Management Branch
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 on behalf of a client 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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons as outlined below.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 Methenex (Methadone Hydrochloride 40mg Naloxone Hydrochloride 2mg) Tablets (effervescent) (NDA 17-491) sponsored by Bristol-Myers, have been voluntarily withdrawn, discontinued from marketing or withheld from sale for safety or efficacy reasons.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 currently FDA-approved drug products and those products relisted after a finding that they were not discontinued from the market for safety or efficacy reasons. We have information to show that the Methenex Tablet NDA was approved by the FDA on July 2, 1974 and appears to have been discontinued on June, 1, 1978 (Attachment I). These documents appear to confirm that FDA approved the product for safety and efficacy. However, based on its date of discontinuance, it may never have appeared in a publication of the Orange Book.

Under FDA regulations a drug product may be submitted as an ANDA if it is the "same as" a reference listed drug product (21 CFR 314.92(a)(1)). The Agency defines a listed drug as "a new drug product that has an effective approval under section 505(c) of the act for safety and effectiveness which has not been withdrawn or suspended under section 505(e)(1) through (e)(5) or (j)(5) of the act." (21 CFR 314.3(b)). 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withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).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, it appears that Methenex Tablets, effervescent, were approved for safety and effectiveness by the FDA. If the approved product was not withdrawn from the market for safety or effectiveness reasons, the product should still be considered a reference listed drug for the purpose of submitting an ANDA. Therefore, because the NDA holder has discontinued marketing of this drug product, it is requested that the FDA determine whether the decision to discontinue marketing of the product, approved under NDA 17-491, was for reasons of safety or effectiveness. If such a determination is made, we also request that the drug product be listed in the discontinued section of the Orange Book, to allow for reference to the listed drug.

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 impacts 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 its 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 that are unfavorable to the petition.

Respectfully submitted,

Robert W. Pollock/mk

Robert W. Pollock
Vice President

RWP/mk

Attachment

cc: G. Davis (Office Of Generic Drugs), L. Lachman

14P1341

NDAs

AN - ACCESSION NUMBER: 4013333
TI - TITLE: ORIGINAL OR SUPPLEMENTAL NDA: METHENEX; METHADONE HYDROCHLORIDE 40MG; NALOXONE HYDROCHLORIDE 2MG
SO - SOURCE: FDA-APPROVED DRUGS SINCE 1938 - LIST EDITION: OCTOBER 1998
NO - NDA NUMBER: 17491
CO - COMPANY: BRISTOL-MYERS
TN - TRADE NAME: METHENEX
GN - GENERIC NAME: METHADONE HYDROCHLORIDE 40MG; NALOXONE HYDROCHLORIDE 2MG
DF - DOSAGE FORM: TABLET (IMMED./COMP. RELEASE), UNCOATED, EFFERVESCENT
RT - ROUTE: ORAL
DT - APPROVAL DATE: 19740702
DD - DISCONTINUED DATE: 19780601

AN - ACCESSION NUMBER: 4013332
TI - TITLE: ORIGINAL OR SUPPLEMENTAL NDA: METHENEX; METHADONE HYDROCHLORIDE 10GM/10.5GM; NALOXONE HYDROCHLORIDE 500MG/10.5GM
SO - SOURCE: FDA-APPROVED DRUGS SINCE 1938 - LIST EDITION: OCTOBER 1998
NO - NDA NUMBER: 17490
CO - COMPANY: BRISTOL-MYERS
TN - TRADE NAME: METHENEX
GN - GENERIC NAME: METHADONE HYDROCHLORIDE 10GM/10.5GM; NALOXONE HYDROCHLORIDE 500MG/10.5GM
DF - DOSAGE FORM: POWDER
RT - ROUTE: ORAL
DT - APPROVAL DATE: 19740702
DD - DISCONTINUED DATE: 19780601

Note: No explanation was located on why these products were discontinued. It may be because Bristol-Myers no longer wished to manufacture a controlled substance. The company is not now listed as a manufacturer of any controlled substance.