Caruso Pharmaceutical Consultation Services

Frank S. Caruso, Ph.D. President

August 5, 2003

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

Dear Sirs:

SUBJECT: CITIZEN PETITION

The undersigned submits this petition 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the commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or efficacy reasons as shown below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Methenex (Methadone Hydrochloride 40 mg, Naloxone Hydrochloride 2 mg) Tablets (effervescent) (NDA 17-491) and Methenex (Methadone Hydrochloride 10 Gm, Naloxone Hydrochloride 0.5 Gm) Powder (NDA 17-490) sponsored by Bristol Myers, have been withdrawn, discontinued from marketing or withheld from sale for safety or efficacy reasons.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 products that are eligible as Abbreviated New Drug Applications (ANDAs). The list referred to is the Orange Book, contains all currently FDA approved drug products and those products relisted after it has been determined that they were not discontinued from marketing because of safety or efficacy reasons. We note that the Methenex Tablet and Powder NDAs were approved on July 2, 1974 and have been discontinued on June 1, 1978 (attachment 1). This confirms that FDA approved the product for safety and efficacy. However, based on the date of discontinuance, it does not reappear, relisted 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 FDA defines a listed drug as "a new drug product that has an active approval under section 505(c) of the act for safety and effectiveness which has not been withdrawn or suspended under section 505 (e)(1) through (e)(5) or (j)(5) of the act." The regulations also provide that the FDA must make a

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determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved, 21CFR 314.161 (a)(1).

As stated above, it appears that Methenex Tablets and Powder NDAs were approved for safety and efficacy by the FDA. If the approved product was not withdrawn from the market because of safety or efficacy reasons, the product should still be considered as 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 discontinuation from marketing of Methenex approved under NDA 17-490 and NDA 17-491 was due to safety or efficacy reasons. If the determination is made that the removal from the market was not related to safety and efficacy, we 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 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 and will be provided, if requested.

D. 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 know to the petitioner that are unfavorable to the petition.

Sincerely,

F. S. Caruso

Frank S. Caruso, Ph.D.

Enclosure (1)

cc: G. Davis (Office of Generic Drugs)

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Attachment 1

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.