DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

August 11, 2003

FILE COPY

Dr. Frank S. Caruso
Caruso Pharmaceutical Consultation Services
900 Ocean Drive, Apt. 1202
Cape May, New Jersey 08204

Dear Dr. Caruso:

Your petition requesting the Food and Drug Administration to determine whether Methenex (Methadone Hydrochloride 40 mg, Naloxone Hydrochloiride 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(Methadone Hydrochloride 10 Gm, Naloxone Hydrochloride 0.5 Gm Powder NDA 17-490 sponsored by Bristol Myers, have been withdrawn, discontinued from marketing or withheld from sale for safety or efficacy reasons, was received by this office on 08/11/2003. It was assigned docket number 2003P-0358/CP 1 and it was filed on 08/11/2003.Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management

2003P-0358

ACK 1