

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75049

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 6
2. ANDA # 75-049
3. NAME AND ADDRESS OF APPLICANT
Geneva Pharmaceuticals, Inc.
2555 W. Midway Blvd.
Broomfield, CO 80038-0446
4. LEGAL BASIS FOR SUBMISSION
Innovator Product: Prozac
Innovator Company: Eli Lilly
Exclusivity Expiration Date: 11/11/99
5. SUPPLEMENT(s): N/A
6. PROPRIETARY NAME: N/A
7. NONPROPRIETARY NAME
Fluoxetine Hydrochloride Capsules, 10 mg and 20 mg
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:

December 31, 1996	Original submission
July 11, 1997	Bio deficiency letter
July 30, 1997	Chemistry deficiency letter
September 5, 1997	Bio amendment/correspondence
November 12, 1997	Methods suitable memo, PhiDO
October 6, 1997	Chemistry amendment
January 16, 1998	Bioequivalence satisfactory
March 16, 1998	Chemistry deficiency letter
August 12, 1998	Chemistry amendment
September 22, 1998	Amendment
September 28, 1998	Labeling satisfactory
January 28, 1998	New correspondence
March 17, 1999	Chemistry deficiency letter
March 23, 1999	Facsimile amendment
June 15, 1999	Tentative Approval Letter
November 3, 2000	Amendment (chemistry & labeling)
November 14, 2000	Labeling satisfactory
November 14, 2000	Amendment (new API source)
December 27, 2000	Telecom
January 5, 2001	Telecom Amendment
April 30, 2001	Tentative Approval
May 18, 2001	Minor Amendment
June 5, 2001	New Correspondence (patent)
June 8, 2001	New Correspondence (patent)
July 30, 2001	New Correspondence (patent)
July 31, 2001	Labeling Amendment

