

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-026

ENVIRONMENTAL ASSESSMENT

NDA 22-026
Amlodipine besylate
2.5 mg, 5 mg, and 10 mg
Orally Disintegrating Tablets
Synthon Pharmaceuticals, Inc.

Environmental Assessment or Claim Of Categorical Exclusion

As written on page 35 of Martin Haber's review dated September 28, 2006, categorical exclusion was requested by the sponsor and accepted by the Division.

**REQUEST FOR EXCLUSION FROM REQUIREMENT FOR
ENVIRONMENTAL IMPACT ANALYSIS STATEMENT**

Pursuant to 21 C.F.R. § 25.31(a), Synthon Pharmaceuticals, Inc. ("Synthon") hereby requests a categorical exclusion from the requirements of an Environmental Impact Analysis Statement.

Under 21 C.F.R. § 25.31(a), a categorical exclusion exists for:

Action on an NDA if the action does not increase the use of the active moiety.

Synthon is requesting FDA to take action by approving its application for Amlodipine besylate 2.5 mg, 5 mg and 10 mg orally disintegrating tablets. This is an action specified in 21 C.F.R. §25.31(a). Synthon meets the other requirements of 21 C.F.R. § 25.31(a) because Synthon's Amlodipine besylate 2.5 mg, 5 mg and 10 mg orally disintegrating tablets will be administered at the same dosage level, for the same duration, and for the same indications as other currently approved forms of amlodipine besylate (e.g., Pfizer, Inc.'s Norvasc® tablets) and thus will not increase the use of the active moiety at issue. Synthon also certifies that, to the best of its knowledge, no extraordinary circumstances exist that would require an Environmental Assessment per 21 C.F.R § 25.15.

Michael H. Hinckle,
VP and General Counsel

Date