DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-299/S-001

Synthon Pharmaceuticals Ltd.
Attention: Susan W. Harts, RN, RAC
Vice President of Regulatory Affairs
6330 Quadrangle Drive, Suite 305
Chapel Hill, NC 27514

Dear Ms. Harts:

We acknowledge receipt of your supplemental new drug application dated July 10, 2003, received July 11, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for paroxetine mesylate 10 mg, 20 mg, 30 mg, and 40 mg Tablets.

Reference is also made to an Agency letter dated July 3, 2003, informing you to submit a "Prior Approval" labeling supplement to your NDA if you wish to market this drug with a proprietary name.

This "Prior Approval" supplemental new drug application proposes the use of the proprietary names of "Odesa" or "Pexeva".

We have completed the review of this supplemental application, and have concluded that your proposed proprietary name of Pexeva is acceptable. However, our Division of Medication Errors and Technical Support (DMETS) has found your proposed tradename of Odesa unacceptable for the following reasons:

In reviewing the proposed proprietary name "Odesa", the primary concerns raised were related to one look-alike and/or sound-alike name. The product considered to have potential for name confusion with Odesa was Adoxa.

Adoxa and Odesa look and sound similar when spoken. Adoxa contains doxycyline and is used as an antibiotic. Adoxa and Odesa look similar since they contain the same number of letters and syllables. The following letters in Adoxa vs. Odesa look similar when scripted: "A" vs. "O", "o" vs. "e", and "x" vs. "s". Additionally, the names share the letters "d" and "a" in the same location (see below). Each name contains three similarly sounding syllables, uh-dox-a vs. oh-des-a. Additionally, the names share an overlapping dosage form (tablet), route of administration (oral), numerically similar strengths (10 mg vs. 100 mg), and dosing regimen (once daily). If the strength in Adoxa is scripted with a trailing zero, the likelihood for confusion may increase. The potential for confusion between Adoxa and Odesa is high given the similarities in name and product characteristics. The inadvertent administration of Adoxa instead of Odesa, may cause a hypersensitivity reaction in a person allergic to doxycycline. A patient inadvertently receiving Odesa instead of Adoxa will remain untreated for a bacterial infection. Additionally, the patient

may experience central nervous system and gastrointestinal side effects from the inadvertent administration of Odesa. In reviewing the container label and package insert for Odesa/Pexeva, DMETS has attempted to focus on safety issues relating to medication errors.

Additionally, DMETS recommends that the 30 count unit-of-use containers have a child-resistant closure (CRC).

Please submit final printed labeling (FPL) identical to the labeling attached to our July 3, 2003 letter and incorporating your approved proprietary name of Pexeva. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-299/S-001." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions regarding this letter, call Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
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