DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-320/S-002

PRAECIS Pharmaceuticals, Inc.
Attention: Carol Hurt
Associate Director, Regulatory Affairs
830 Winter Street
Waltham, MA 02451-1420

Dear Ms. Hurt:

Please refer to your supplemental new drug application dated May 17, 2005, receivedMay 18, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plenaxis® (abarelix for injectable suspension).

This "Changes Being Effected" supplemental new drug application provides for the revision of the Hospital Pharmacy's Acceptance of Responsibilities Form.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (Hospital Pharmacy's Acceptance of Responsibilities Form) dated May 17, 2005, as enclosed.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-320/S-002**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 827-7260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Daniel A. Shames
9/8/2005 05:47:18 PM