DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-249/S-009, S-010, S-011

Kos Life Sciences, Inc.
Attention: Valerie Ahmuty
Director, Regulatory Affairs
220 N. Commerce Parkway, Suite 300
Weston, FL 33326-3258

Dear Ms. Ahmuty:

Please refer to your supplemental new drug applications submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Advicor® (niacin extended-release/lovastatin tablets):

Supplement -009- Submitted October 31, 2005; Received November 1, 2005
Supplement -010-Submitted October 28, 2005; Received November 1, 2005
Supplement -011-Submitted December 1, 2005; Received December 2, 2005

We acknowledge receipt of your submission dated March 23, 2006 to Supplement -011.

Supplement -009, submitted as a Changes Being Effected supplement, proposes to revise the DESCRIPTION section of the package insert to clarify that the extended release niacin is an antihyperlipidemic agent and not a vitamin.

Supplement -010, submitted as a Changes Being Effected supplement, proposes to revise the DESCRIPTION and HOW SUPPLIED sections of the package insert necessitated with the reintroduction of distribution of the 750 mg/20 mg tablet. The application also provides for a bottle label for this strength product.

Supplement -011, submitted as a prior approval supplement, proposes to add a 1000 mg/40 mg tablet and associated labeling revisions.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert, bottle labels for 750 mg/20 mg and 1000 mg/40 mg tablet presentations).

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 21-249/S-009, S-010, S-011**." 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Acting Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures: Package Insert
Bottle Label 750 mg/20 mg Tablets, 90 count
Bottle Label 1000 mg/40 mg Tablets, 90 count

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

/s/

Eric Colman
4/27/2006 08:50:28 AM
Eric Colman for Mary Parks