DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-249/S-001

Kos Pharmaceuticals, Inc.
Attention: David H. Warnock, Ph. D.
Executive Director, Regulatory Affairs
14875 NW 77th Avenue, Suite 100
Miami Lakes, FL 33014

Dear Dr. Warnock:

Please refer to your supplemental new drug application dated August 6, 2002, received August 7, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advicor (niacin extended-release and lovastatin) Tablets.

We acknowledge receipt of your submission dated May 8, 2003.

Your submission of May 8, 2003, constituted a complete response to our February 4, 2003, action letter.

This "Changes Being Effected" supplemental new drug application provides for clarification of the dosage titration in the **DOSAGE AND ADMINISTRATION** section of the package insert.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 8, 2003.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
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/

David Orloff

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