DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-381/S-006

OCT 28 1999

Kos Pharmaceuticals, Inc.
Attention: David Warnock,Ph.D.
Director, Regulatory Affairs
1001 Brickell Bay Drive, 25th Floor
Miami, Florida 33131

Dear Dr. Warnock:

Please refer to your supplemental new drug application dated December 23, 1998, received December 28, 1999, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Niaspan (niacin extended-release) Tablets.

We acknowledge receipt of your submissions dated January 5, August 5, 24, 25, and 27, September 13, 15, 23, 27, and 29, and October 12, 1999.

This supplemental new drug application provides for the addition of the phrase "and to increase HDL-C" to item number one in the list of indications in the INDICATIONS AND USAGE section of the Niaspan package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted October 12, 1999).

Please submit 20 copies of the FPL as soon as it is available, in no case 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 supplement NDA 20-381/S-006." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27).

Although you have not requested a waiver of this requirement, we are waiving the requirement for pediatric studies for Niaspan. This decision is based on our assessment of the risks and benefits of pediatric use of this drug for the approved indications.

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, contact Margaret Simoneau, R.Ph., Regulatory Management Officer, at (301) 827-6418.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research