DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-268/S-009

Kos Life Sciences
Atten: David W. Warnock, Ph.D.
2200 North Commerce Parkway, Suite 300
Weston, FL 33326-3258

Dear Dr. Warnock:

Please refer to your supplemental new drug application dated March 10, 2005, received March 11, 2005, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for:

- Teveten HCT® (eprosartan mesylate/hydrochlorothiazide) tablets, 600/12.5, 600/25 mg.

We acknowledge receipt of your submissions dated March 22, 2005; April 14, 2005; July 5, 2005 and July 11, 2005.

This supplemental new drug application provides for changes to the Opadry film coat, changes to regulatory analytical procedures, changes to the dissolution specifications and minor changes to the manufacturing process.

We completed our review of this supplemental new drug application, as amended. This supplement is approved.

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

If you have any questions, please call LCDR Cheryl Ann Borden, Regulatory Project Manager, at (301) 594-5312.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDCI for
The Division of Cardio-Renal Drug Products, (HFD-110)
DNDCI, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar

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