CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-532

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-532

Sankyo Pharma, Inc.
Attn: Mr. Albert Yehaskel
399 Thornall Street, 11th Floor
Edison, New Jersey 08837

Dear Mr. Yehaskel:

Please ~~refer~~ to your new drug application (NDA) dated August 5, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benicar HCT (olmesartan medoxomil/hydrochlorothiazide) 20 mg/12.5 mg, 40 mg/12.5 mg, and 40 mg/25 mg Tablets.

We acknowledge receipt of your submissions dated September 5, October 3 and 24, December 2 and 26, 2002, and January 17, 22 (two), and 31, February 28, March 10 (two), 12 (two), 14 (two), 19, and 28, and April 3 (two) and 17 (two), May 29, and June 2 and 3, 2003.

This new drug application provides for the use of Benicar HCT (olmesartan medoxomil/hydrochlorothiazide) 20 mg/12.5 mg, 40 mg/12.5 mg, and 40 mg/25 mg Tablets for the treatment of hypertension.

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

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, and the immediate container and carton labels included in you April 3, 2003 submission.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-532.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

The following dissolution method and specifications are recommended:

CS-866 (olmesartan medoxomil)

Medium:	900 ml, JP fluid 2, pH 6.8, 37°C
Apparatus:	USP II (paddle)
Speed:	50 rpm
Specifications:	Q not less than — at 45 minutes

HCTZ

Medium:	900 ml, JP fluid 2, pH 6.8, 37°C
Apparatus:	USP II (paddle)
Speed:	50 rpm
Specifications:	Q not less than — at 15 minutes

Please note that based on the provided stabiltiy data, the expiration date for Benicar HCT tablets packaged in HDPE bottles and Aluminum/Aluminum blisters is 18 months, when stored at 20-25°C.

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 contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure