DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-350/S-003

Food and Drug Administration
Rockville MD 20857

R & R Registrations
U.S. Agent for Recip, AB
Attention: Ronald G. Leonardi, Ph.D.
9915 Cam. Chirimolla
San Diego, CA 92196-2069

OCT 28 2003

Dear Sir:

This is in reference to your supplemental new drug application dated July 3, 2003 submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Potassium Iodide Tablets USP, 65 mg.

The supplemental application, submitted as a "Prior Approval Supplement", provides for the extension of the expiration dating period to 36 months.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

Paul Schwartz for

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research