



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 18-664/S-006

JAN - 7 2004

Anbex, Inc.
Attention: Alan Morris
[REDACTED]
Branchville, NJ 07826

Dear Sir:

This is in reference to your supplemental new drug application dated November 11, 2003 submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Iosat[®] (Potassium Iodide Tablets USP), 130 mg.

This supplemental application, submitted as "Prior Approval Supplement", provides for the extension of the expiration dating period to seven years.

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,

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