ANDA 75-135/S-001

Upsher-Smith Laboratories, Inc.
Attention: Mark Robbins
14905, 23rd Avenue North
Minneapolis, MN 55447-4709

DEC 2 1999

Dear Sir:

This is in reference to your supplemental new drug application dated February 15, 1999, under section 505 (j), of the Federal Food, Drug and Cosmetic Act, regarding your abbreviated new drug application for Amiodarone Hydrochloride Tablets 200 mg

The supplemental application submitted as "Prior Approval Supplements" provides for an alternate site for [redacted]

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,

/S/

12/2/99

Florence S. Fang
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research