ANDA 75-135/S-003

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

SEP 24 1999

Dear Sir:

This is in reference to your supplemental new drug application dated September 16, 1999, submitted pursuant to 21 CFR 314.70(c)(Special Supplement - Changes Being Effected) regarding your abbreviated new drug application for Pacerone® (Amiodarone HCl) Tablets, 200 mg.

The supplemental application provides for revisions to the WARNINGS and PRECAUTIONS sections of the package insert labeling.

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

However, at the time of next printing please make the following revisions:

1. CLINICAL PHARMACOLOGY

   Monitoring Effectiveness, second sentence - ... consensus on some aspects:

2. INDICATIONS AND USAGE

   a. First sentence - Because of its life-threatening ...

   b. Combine the ultimate and penultimate paragraphs.

The above changes may be submitted in an annual report provided that they are described in full.

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/

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75-135/S-003

/S/

APPROVAL LETTER - SINGLE SUPPLEMENT

/S/

APPEARS THIS WAY
ON ORIGINAL