CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-594

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-594

International Medication Systems, Limited
Attention: Mr. Stephen A. Campbell
Vice President, Regulatory Affairs
1886 Santa Anita Ave.
South El Monte, CA 91733

Dear Mr. Campbell:

Please refer to your new drug application (NDA) dated October 31, 2002, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Amiodarone Hydrochloride Injection, 50 mg/ml, 3 ml and 18 ml pre-filled syringes.

We acknowledge receipt of your submissions dated September 5, 10 and 18, and December 2, 2003.

The December 2, 2003 submission constituted a complete response to our September 5, 2003 action letter.

This new drug application provides for the use of Amiodarone Hydrochloride Injection, 50 mg/ml for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation, hemodynamically unstable ventricular tachycardia in patients refractory to other therapy and treatment of patients with ventricular tachycardia or ventricular fibrillation for whom oral amiodarone is indicated, but who are unable to take oral medication.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (package insert and immediate container and carton labels submitted December 2, 2003).

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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

Please submit one market package of the drug product when it is available.

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

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. Russell Fortney
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

/s/

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Doug Throckmorton
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