DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090924

GeneraMedix Inc.
Attention: Leann Clymer
150 Allen Road
Suite 110
Liberty Corner, NJ 07938

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 30, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ibutilide Fumarate Injection, 0.1 mg/mL, packaged in 10 mL single-dose vials.

Reference is also made to your amendments dated March 12, April 28, May 7, August 25, October 9, and December 18, 2009.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Ibutilide Fumarate Injection, 0.1 mg/mL, packaged in 10 mL single-dose vials to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Corvert, 0.1 mg/mL single-dose vial, of Pfizer – Pharmacia & Upjohn Company.

The reference listed drug product (RLD) referenced in your application, Corvert, 0.1 mg/mL single-dose vial, of Pfizer - Pharmacia & Upjohn was subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book" U.S. Patent No. 5,155,268 (the '268 patent) expired on December 28, 2009.

Your ANDA contains a Paragraph III Certification to the listed patent under section 505(j)(2)(A)(vii)(III) of the Act. This certification states that (b) (4) will not market your Ibutilide Fumarate Injection, 0.1 mg/mL, packaged in 10 mL single-dose vials prior to the expiration of the patent. The agency recognizes the patent has expired, no longer precluding the agency from approving your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence – SPL for Approved ANDA 090924***".

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-90924	ORIG-1	GENERAMEDIX INC	IBUTILIDE FUMARATE

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

/s/

GARY J BUEHLER
01/11/2010