DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 3, 2006

Matthew D. Peterson
FoxKiser
750 17th Street, NW
Suite 1100
Washington, DC 20006

Dear Mr. Peterson,

This letter is in response to your letter dated April 28, 2006, requesting that the Food and Drug Administration confirm certain information regarding NitroMed Inc.'s approved drug product, BiDil® Tablets (isosorbide dinitrate and hydralazine hydrochloride), 20 mg/37.5 mg (NDA 20-727).

As reflected in the current *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book), FDA has not approved any drug product under section 505 of the Federal Food, Drug, and Cosmetic Act that is designated as therapeutically equivalent (i.e., substitutable) to BiDil. In addition, neither approved labeling for isosorbide dinitrate drug products nor approved labeling for hydralazine hydrochloride drug products contains information regarding the use of these drug products for the treatment of heart failure.

Thank you for contacting the Office of Executive Programs at CDER.

Sincerely,

Christine M. Bechtel RN, MSN

Christine M. Bechtel RN, MSN
Director, Executive Operations Staff
Center for Drug Evaluation and Research
U.S. Food and Drug Administration