FOXKISER

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April 26, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**CITIZEN PETITION**

The undersigned submits this petition under 21 CFR § 10.30 to request the Commissioner of Food and Drugs to confirm that the Food and Drug Administration has not determined that any drug is therapeutically equivalent or AB-rated to BiDil® (isosorbide dinitrate and hydralazine hydrochloride).

A. Action Requested

The petitioner seeks confirmation from the Food and Drug Administration of the following:

1. That FDA has not determined any drug to be therapeutically equivalent to BiDil.

2. That FDA has not designated any drug AB-rated to BiDil.

B. Statement of Grounds

NitroMed, Inc. is a research-based pharmaceutical company that manufactures BiDil and focuses its research on therapies targeted to improving treatment of underserved patient populations. NitroMed's BiDil new drug application (NDA) was approved in 2005 for the treatment of heart failure in self-identified black patients.

BiDil is a fixed-dose combination of isosorbide dinitrate and hydralazine hydrochloride. These chemical entities are marketed as individual agents for other indications in different dosages (isosorbide dinitrate is indicated for angina, and hydralazine hydrochloride is indicated for hypertension). Neither is indicated for the treatment of heart failure, and neither is approved for use with the other. Consequently, both FDA's *Orange Book* (attachment A) and its Drugs@FDA website (attachment B) list no drugs as being therapeutically equivalent or AB-rated to BiDil.

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However, NitroMed has received reports that information is being disseminated regarding the availability of "generic" versions of BiDil. Consequently, we ask FDA to confirm that it has not determined that any drug is therapeutically equivalent or AB-rated to BiDil.

C. Environmental Impact

The petitioner claims categorical exclusion from the requirements for an environmental assessment under 21 CFR § 25.31.

D. Economic Impact

A statement of economic impact will be provided if requested by the Commissioner following review of this petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

William E. Holtz
Counsel to NitroMed, Inc.