DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-377/S-057

Women First HealthCare
Attention: Doranne Frano
Director, Regulatory Affairs
12220 El Camino Real Drive, Suite 400
San Diego, CA 92130

Dear Ms. Frano:

Please refer to your supplemental new drug application dated August 10, 2000, received August 11, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bactrim™ (trimethoprim and sulfamethoxazole) Tablets.

We acknowledge receipt of your submission dated October 30, 2002.

This supplemental new drug application provides for the addition of a ***Geriatric Use*** subsection in the **PRECAUTIONS** section in accordance with the "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of 'Geriatric Use' Subsection in the Labeling" Final Rule.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. In the **REFERENCES** section, the following two citations should be added as references 8 and 9, respectively:

   "Marinella, Mark A. 1999. Trimethoprim-induced hyperkalemia: An analysis of reported cases. *Gerontol*. 45:209-212."

   "Margassery, S. and B. Bastani. 2002. Life threatening hyperkalemia and acidosis secondary to trimethoprim-sulfamethoxazole treatment. *J. Nephrol.* 14:410-414."

2. The statement in the ***Drug Interactions*** subsection of the **PRECAUTIONS** section should be changed to include references 8 and 9 as follows: "In the literature, three cases of hyperkalemia in elderly patients have been reported after concomitant intake of trimethoprim/sulfamethoxazole and an angiotensin converting enzyme inhibitor. [8, 9] "

3. The remaining references and corresponding citations, particularly those starting in the **Microbiology** subsection, should be renumbered and updated accordingly.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (package insert submitted October 30, 2002). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-377/S-057." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Ms. Beth Duvall-Miller, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure

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

/s/

Janice Soreth

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