DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-377/S-058

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 January 23, 2002, received January 24, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bactrim™ (trimethoprim and sulfamethoxazole) Tablets and DS (double strength) Tablets.

We acknowledge receipt of your submissions dated August 9 and August 22, 2002. Your submission of August 22, 2002 constituted a complete response to our July 24, 2002 action letter.

This supplemental new drug application provides for the transfer of drug product manufacturing from Roche Laboratories to Mutual Pharmaceuticals. The formulation, manufacturing site, manufacturing equipment, and manufacturing process of sulfamethoxazole/trimethoprim tablets and Bactrim™ Tablets manufactured by Mutual Pharmaceuticals are the same except that Bactrim™ Tablets manufactured by Mutual Pharmaceuticals will have different imprinting than the sulfamethoxazole/ trimethoprim tablets manufactured by Mutual Pharmaceuticals to reflect WFHC markings.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 9, 2002.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Beth Duvall-Miller, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{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

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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