



NDA 17-376/S-059
17-598/S-041

Monarch Pharmaceuticals, Inc.
Attention: Karen C. Baker
Senior Manager, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Ms. Baker:

Please refer to your supplemental new drug applications dated March 23, 2007, received March 26, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

- Septra[®] and Septra[®] DS (trimethoprim/sulfamethoxazole) tablets (NDA 17-376)
- Septra[®] (trimethoprim/sulfamethoxazole) suspension (NDA 17-598)

These “Changes Being Effected” supplemental new drug applications provide for revisions to the package inserts to include information relative to recent epidemiologic and scientific data regarding *Clostridium difficile* associated disease (CDAD).

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 23, 2007.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 J. Christopher Davi, MS Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on March 23, 2007

**This is a representation of an electronic record that was signed electronically and
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/s/

Kathrine Laessig
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