DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018657/S-028

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Amy Giertych
Senior Director, Global Regulatory Affairs
1620 Waukegan Road MPGR-AL
McGaw Park, IL 60085

Dear Ms. Giertych:

Please refer to your Supplemental New Drug Application (sNDA) dated March 5, 2009, received March 10, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Flagyl I.V. (metronidazole injection, USP), RTU in Viaflex Plus Container.

We also acknowledge receipt of your amendment dated September 8, 2011. This submission constituted a complete response to our October 22, 2009, action letter.

This "Prior Approval" supplemental new drug application proposes container labeling enhancements designed to increase product differentiation, label readability, and to help reduce the potential for medication error.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed container and overpouch labels submitted on September 8, 2011, as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 018657/S-028**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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 Caroline D. Fukuda, MHA, Regulatory Project Manager, at (301) 796-4757.

Sincerely,

{See appended electronic signature page}

John Farley, MD, MPH
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
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/

JOHN J FARLEY
05/25/2012