DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-064/S-014

Procter & Gamble Pharmaceuticals, Inc.,
Health Care Research Center
Attention: Victoria Ireland
U.S. Regulatory Affairs
8700 Mason-Montgomery Road
Mason, OH 45040-9642

Dear Ms. Ireland:

Please refer to your supplemental new drug application dated May 29, 2003, received May 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrobid® (nitrofurantoin monohydrate/macrocrystals) Capsules. This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This 'Changes Being Effected in 0 days" supplemental new drug application provides for labeling changes to be in compliance with the 'Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use," Final Rule, as published in the Federal Register, Vol. 68, No. 25, February 6, 2003.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 30, 2003.

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, HFD-410
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 LT Raquel Peat, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

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

Enclosure: FPL

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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