



NDA 16-620/S-065

Procter & Gamble Pharmaceuticals, Inc
Health Care Research Center
Attention: Victoria Ireland
U.S. Regulatory Affairs
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Ms. Ireland:

Please refer to your supplemental new drug application dated August 21, 2003, received August 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrodotin[®] (nitrofurantoin macrocrystals) Capsules. We note that 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 supplemental application, submitted as a "Supplement - Changes Being Effectuated in 0 days" supplement, proposes the following change to be in compliance with the systemic antibacterial drug products labeling regulations as found in 21 CFR 201.24.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 22, 2003.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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.

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If you have any questions, call LT Raquel Peat, 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

Enclosure: Labeling

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

Janice Soreth

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