DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-620/S-064

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

Dear Ms. Ireland:

Please refer to your supplemental new drug application dated August 2, 2002, received August 5, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrodantin® (nitrofurantoin macrocrystals) Capsules.

This supplemental new drug application provides for the addition of a **Geriatric Use** subsection in the **PRECAUTIONS** section in accordance with the "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of 'Geriatric Use' Subsection in the Labeling" Final Rule.

We 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 2, 2002.

However, at the time of the next printing, please revise your FPL as follows:

1. In the first sentence of the **Geriatric Use** subsection, the word "nitrofurantoin" should be changed to "Macrodantin".

2. In the second sentence of the **Geriatric Use** subsection, the words "in the literature" should be deleted, since they are not included in the sentence under 21 CFR 201.57(f)(10)(ii)(A).

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) 827-2128.

Sincerely yours,

{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

2/4/03 04:29:00 PM