

PEDINOL PHARMACAL, INC.

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Letter Regarding Possibility of Rare Tablet Mix-Up

January 24, 2012

Dear Pharmacist,

Our contract manufacturer (Novartis Consumer Healthcare) has notified us that several of their own Over-the-Counter "OTC" products have been cited by the FDA for including "stray" or different product tablets packaged together improperly. After a thorough investigation and analysis, we have determined that to the best of our knowledge NO PEDINOL PRODUCTS WERE EFFECTED. In an over-abundance of caution, Pedinol is informing you of this matter. In essence, Pedinol has received no product complaints of stray tablets in its Gris-PEG® (griseofulvin ultramicrosize) 125mg or 250mg tablets. Because Pedinol's Gris-PEG® product is pharmacist dispensed by prescription only, the chances of a product mix-up are even further reduced. As pharmacists, we ask you to be extra vigilant when dispensing Gris-PEG® tablets. The tablets involved appear to have been limited to OTC products for consumers only.

The tablets manufactured by our third party manufacturer are:

- Gris-PEG® (griseofulvin ultramicrosize) 250mg, NDC 0884-0773-04
- Gris-PEG® (griseofulvin ultramicrosize) 125mg, NDC 0884-0763-04

As a brief background, production of these products has been temporarily suspended by our contract manufacturer in order for the manufacturer to implement manufacturing process improvements. These improvements are intended to address rare instances of errors in the packaging of the tablets, potentially resulting in product mix-ups. Pedinol is not aware of any product mix-ups with respect to these products at the pharmacy or patient level. Pedinol has no reported incidents of adverse events occurring due to any product mix-ups. We believe the likelihood of a product mix-up reaching a patient is remote.



Pedinol's principal concern is the health and well-being of its patients. In order to minimize the impact of this manufacturing issue on patients and to ensure patients are taking only the product prescribed for them, we recommend that you take the following steps:

- As a precautionary measure, as you dispense Gris-PEG[®], PLEASE OPEN ALL BOTTLES BEFORE DISPENSING AND COMPLETE A VISUAL INSPECTION OF THE ENTIRE CONTENTS TO ENSURE THAT EACH BOTTLE CONTAINS THE CORRECT TABLETS. YOU CAN VERIFY THE APPEARANCE OF THESE PRODUCTS BY CONFIRMING THE TABLETS MATCH THE IMAGES IN THE VISUAL GUIDE FOUND ON WWW.GRIS-PEG.COM. A COPY OF THE VISUAL AID IS ENCLOSED FOR YOUR USE.
- For any issues with Gris-PEG[®] not yet dispensed or Gris-PEG[®] issues reported by a patient to you, please contact Pedinol at 1-800-733-4665 for further information.

Please contact Pedinol at 1-800-733-4665 should you have any additional questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary Strauss", with a long horizontal flourish extending to the right.

Gary Strauss,
Chief Executive Officer