

AUG 28 2009

PEDINOL PHARMACAL, INC.

30 Banli Plaza North, Farmingdale, NY 11735 Phone: (631) 293-9500 / 1-800-PEDINOL Fax: (631) 293-7359 www.pedinol.com
August 25, 2009

VIA ELECTRONIC MAIL AND OVERNIGHT DELIVERY

Jimmy Mitchell, R.Ph., M.P.H., M.S.
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Parklawn Building
Mail Stop 10C-03
Rockville, Maryland 20857

Re: Refunds to Section 340B Program Participants for Gris-PEG®

Dear Mr. Mitchell :

As Executive Vice President of Pedinol Pharmacal, Inc. ("Pedinol"). I am writing to notify you of Pedinol 's intent to make refunds to participants in the Section 340B Program that purchased Pedinol 's Gris-PEG® (griseofulvin ultramicrosize) product line between January 1, 2004, and October 31, 2008, consistent with Pedinol's previous discussions with the Office of Pharmacy Affairs ("OPA").

Pedinol is a small, family-owned specialty pharmaceutical company that focuses primarily on treatments for podiatric, pediatric, and dermatological conditions. Pedinol is committed to compliance with all requirements of the Section 340B Program and works toward continuous improvement of its practices underlying compliance with those requirements. In furtherance of this goal, Pedinol has discovered an error in the Base Date Average Manufacturer Prices used to calculate the "additional rebate" portions of the Unit Rebate Amounts for Gris-PEG® under the Medicaid Drug Rebate Program. Pedinol has reported this error to the Centers for Medicare and Medicaid Services and has initiated a Prior Period Adjustment for all affected Medicaid rebate periods.

Pedinol also has completed its assessment of the extent to which this inadvertent error affected the prices it charged Section 340B participants for the Gris-PEG® product line National Drug Codes ("NDCs") 0884-0763-04, 0884-0773-04, and 0884-0773-50 -over the affected time period of January 1, 2004, through October 31, 2008. The aggregate amount due to approximately 800 Section 340B Program participants is approximately \$585,000. Pedinol anticipates initiating payment of the refunds immediately and proposes to complete payment of all rebates by March 31, 2010. Any Section 340B Program participant that purchased any of the Gris-PEG® NDCs listed above during the affected time period that has questions regarding the refund it receives or that does not receive a refund by March 31, 2010, should contact Josie Brown, Manager of Managed Care Sales & Government Programs, at jbrown@pedinol.com or 800.733.4665 ext. 327.

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If OPA objects to the manner in which Pedinol proposes to proceed, or if you have any questions or concerns regarding this issue, please contact Pedinol's outside counsel at Epstein Becker & Green, P.C.:

Constance Wilkinson at 202.861.1378 or cwilkinson@ebglaw.com; or Benjamin Martin at 202.861.1853 or bmartin@ebglaw.com.

Pedinol hereby consents to OPA posting this letter to the OPA website.

Sincerely,
Gary Strauss
Executive Vice President
Pedinol Pharmacal, Inc.

Copy (by electronic mail only);
Mr. Devin Williams