

Stephen R. Cunningham, MD Vice President & Head USCDMA Novartis Pharmaceuticals Corporation One Health Plaza Bidg. 701/184 East Hanover, NJ 07936

Tel 862.778.4304 Fax 973.515.0917 Internet: stephen.cunningham @pharma.novartis.com

May 5, 2004

## Distribution Changes for Lamprene®

## Dear Pharmacist:

As a regular dispenser of Lamprene® (clofazimine), you may already be aware that Novartis has joined with the World Health Organization (WHO) to eradicate leprosy. As part of this commitment, we will provide Lamprene *free of charge* to patients around the world.

In the United States, our partner in this effort is the National Hansen's Disease Programs (NHDP), a unit of the US Department of Health and Human Services, based in Baton Rouge, Louisiana. When US wholesalers, pharmacy chains and individual pharmacies deplete their inventories of Lamprene later this year, the product will no longer be sold in pharmacies and will only be distributed under an Investigational New Drug (IND) application held by NHDP.

Beginning approximately July 1, 2004, or whenever you can no longer acquire Lamprene through your normal supplier, any requests that you receive for Lamprene for the treatment of leprosy should be directed to:

Renee Painter
Administrative Officer
Laboratory Research Branch
RPAINT1 @ LSU.EDU
Skip Bertman Drive
Baton Rouge LA 70803
Phone: (225) 578-9861
Fax: (225) 578-9856

To receive Lamprene for use in the treatment of leprosy, a physician will need to register as an investigator under the IND held by NHDP. Ms. Painter will provide physicians with the necessary paperwork for this process.

In addition, the FDA has requested that Lamprene be available for the treatment of multidrug-resistant tuberculosis (MDRTB). For this purpose, Lamprene will be distributed via single patient INDs administered by the Food and Drug Administration (FDA). All requests for use of Lamprene for the treatment of MDRTB must be directed to:

Division of Special Pathogen and Immunologic Drug Products (HFD-590) Center for Drug Evaluation and Research Food and Drug Administration (301) 827-2127

Upon approval of the patient IND, the FDA will request that NHDP to distribute Lamprene directly to the prescriber.

If you have any questions about this process, please contact Novartis at 1-888-NOW-NOVA between 9:00 AM and 5:00 PM Eastern Time, Monday through Friday.

Sincerely,

Stephen Cunningham, MQ

Vice President and Head

US Clinical Development & Medical Affairs

Novartis Pharmaceuticals Corporation