

Heyltex Corporation

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BY REGISTERED MAIL

Final Letter sent to Heyl Pharmacy Clients
Via Registered Mail 8/31/2004

Dear,

We are writing with regard to DMPS (sodium RS-2,3-dimercapto-1propane sulfonate), a bulk active pharmaceutical ingredient ("API") which you have purchased in the past from Heyltex Corporation ("Heyltex") for purposes of pharmacy compounding. DMPS is manufactured by HEYL Chemisch-pharmazeutische Fabrik, GmbH & Co. K.G. of Germany ("Heyl"), Heyltex's parent company. This letter is to inform you of recent reports that Heyltex has received regarding adverse reactions experienced by some patients who have been treated with compounded transdermal drug products containing DMPS.

The finished-dosage-form drugs Dimaval® (DMPS) [capsules] and DMPS-Heyl® (DMPS) [parenteral (intravenous or intramuscular)] have been approved for use in Germany by BfArM, Germany's counterpart to the U.S. Food and Drug Administration ("FDA"), for the treatment of acute and chronic poisoning with mercury and lead. A new drug application, ("NDA"), has not been submitted in the United States for either Dimaval® or DMPS-Heyl®, and neither drug has been approved by the FDA. Similarly, neither drug has been approved by Health Canada.

Heyltex has received telephone calls in recent weeks from parents of children who have been treated with compounded transdermal dosage-form drug products containing DMPS. These parents have reported that their children have developed application site reactions which vary in severity from a mild skin rash to severe reactions involving bleeding and scarring. It is unknown at this time if the DMPS in these multi-ingredient formulations is the causative agent of the skin reactions. We have attached information from the Heyltex Scientific Monograph, 1997 Edition, regarding the known adverse reactions for the oral and parenteral dosage form of DMPS.

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Heyl is not aware of any controlled clinical trials published in the scientific literature that might establish the safety and efficacy of DMPS when delivered transdermally, and Heyl is not conducting any clinical studies. Consistent with the scientific literature and BfArM's approval of Dimaval® (DMPS) and DMPS-Heyl®, Heyl recommends that the DMPS only be compounded into an oral or injectable dosage form. Based on scientific literature, an injectable form may be less efficacious than oral administration. The injectable form is recommended when oral administration is not possible.

Given the recent reports of adverse reactions, we recommend that you exercise caution and consult with the prescribing physician if you receive a prescription or order for a compounded transdermal DMPS product.

Please do not hesitate to contact me if you have any questions.

Sincerely,

Pam Floener
Representative for U.S. & Canada
HEYL Chemisch-pharmazeutische Fabrik, GmbH

Encl; Sec. 7.4 - 7.5.5 from Heyltex Scientific Monograph on DMPS, 1997