STATEMENT BY USP THAT THE SPECTREX, LIGHT DIFFRACTION METHOD OF COUNTING PARTICLES IN PHARMACEUTICAL PRODUCTS IS ACCEPTABLE BY USP.

James W. Kelly, Ph.D, Scientist and Liaison
Parenteral Products-Industrial Expert Committee
U.S. Pharmacopeia. September 2005

From: James Kelly [mailto:JWK@usp.org]
Friday, September 23, 2005

To : John M. Hoyte, President
Spectrex Corporation
Redwood City, CA

USP 28 - NF 23 General Notices, under Tests and Assays, Procedures, states that "Compliance may be determined also by the use of alternative methods, chosen for advantages in accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction or in other special circumstances. Such alternative or automated procedures or methods shall be validated. However, Pharmacopeia standards and Procedures are interrelated; therefore, where a difference appears or in the event of dispute, only the result obtained by the procedure given in this Pharmacopeia is conclusive."

Basically, this means that for <788> Particulate Matter in Injections, utilization of a Light Diffraction technique could be used as an alternative method provided that the analytical method used is validated. For alternative methods, resulting data must be equal to or superior to those results obtained by the Light Obscuration method in <788>. In the case of a dispute or investigation by regulatory agencies such as the FDA, the Light Obscuration method in <788> will take precedence for final data and results.

Sincerely,

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