



JUN 20 2006

John Schroer
Regulatory Manager
3V Inc.
P.O. Box 2810
Georgetown, SC 29442

Dear Mr. Schroer:

We are writing in response to the time and extent application (TEA) that you submitted on September 16, 2005, for the sunscreen ingredient Uvasorb HEB (INCI name: diethylhexyl butamido triazone). You submitted two versions of the TEA: a version identified as "CONFIDENTIAL" and a version identified as a "PUBLIC COPY" (i.e., excluding confidential information).

We agree that the information excluded from the "PUBLIC COPY" of the TEA represents confidential commercial information as defined in 5 U.S.C. 552(b)(4) and 21 CFR 20.61(b) and (c). The following information included in the "CONFIDENTIAL" version of the TEA has been redacted from the "PUBLIC COPY:"

- Table 1. Data from the columns titled "Cumulative Weight of AI Sold," "Consumer Product Package Sizes," and "Total no. of dosage units"
- Attachment III. Method of Synthesis and Purification
- Attachment IV. Specifications and Analytical Methods
- Attachment VII. Letters from Customers

In place of the data from Table 1, the "PUBLIC COPY" includes the total number of dosage units sold in Europe and in South America in Section III of the TEA.

As requested, we will place the "PUBLIC COPY" of your TEA on public display at the Division of Dockets Management (Docket No. 2006O-0231). If you have any questions or comments regarding this matter, please contact Dr. Michael Koenig at 301-796-2090.

Sincerely,

Susan Johnson, Ph.D.
Acting Director
Division of Nonprescription Regulation Development
Office of Nonprescription Products
Center for Drug Evaluation and Research

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