KAH Specialty Products, LLC

Report Reaction, LLC

On 12/22/06 a law was passed and signed entitled **The Dietary Supplement and Nonprescription Drug Consumer Protection Act.**

This laws states:

"(1) IN GENERAL.—The manufacturer, packer, or distributor whose name (pursuant to section 502(b)(1)) appears on the label of a nonprescription drug marketed in the United States (referred to in this section as the 'responsible person') shall submit to the Secretary any report received of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug.

(d) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:
"(x) If it is a nonprescription drug (as defined in section 760) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in section 760) may receive a report of a serious adverse event (as defined in section760) with such drug.'

Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for dietary supplements, and may be accompanied by additional information.

The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

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