## FOI 14-9000

## CAERS Reports Allegedly Related to Products by Vemma Nutrition Company

Search Terms: Products Listed

FDA's Center for Food Safety and Applied Nutrition's (CFSAN's) Adverse Event Reporting System (CAERS) is a post-market surveillance system that collects reports about adverse events and product complaints that are allegedly related to CFSAN-regulated products. These products include conventional foods (and beverages), dietary supplements, infant formulas and cosmetics.

The adverse event reports about a product and the total number of adverse event reports for that product in CAERS only reflect information AS REPORTED and do not represent any conclusion by FDA about whether the product actually caused the adverse events. The attached reports are what have been entered into CAERS during the requested dates (the search date used was the CAERS entered date, as opposed to other dates such as the FDA Received Date or CAERS Received Date, etc.).

The reports submitted to FDA vary in the quality and reliability of the information provided. Some reports to FDA do not necessarily include all relevant data, such as whether an individual also suffered from other medical conditions or used other products or medications at the same time. Reports may not include accurate or complete contact information for FDA to seek further information about the event, or complainants may choose not to participate in a follow-up investigation. When important information is missing from a report, it is difficult for FDA to fully evaluate whether the product caused the adverse event or simply coincided with it. There also may be duplicate reports in CAERS for the same adverse event because multiple people (such as an injured consumer and a health care provider who treated him or her) may have submitted reports.

Because CAERS is constantly updated with new information, the number of reports for a given product and the content of individual reports may change over time.

Report #	RA_CAERS Created Date	Brand/Product Name	PRM_Firm Name	Symptoms	Outcomes
143400	09/14/2011	VEMMA PM	VEMMA VERVE NUTRITION COMPANY	LIVER FUNCTION TEST ABNORMAL	HOSPITALIZATION
	09/14/2011	VERVE ENERGY DRINK	VEMMA VERVE NUTRITION COMPANY		
166998	06/24/2013	VEMMA BOD-E CLEANSE DIETARY SUPPLEMENT	VEMMA NUTRITION COMPANY	NAUSEA, DIARRHOEA, ABDOMINAL PAIN, ABDOMINAL DISTENSION	VISITED AN ER, HOSPITALIZATION
	06/24/2013	VEMMA BOD-E CLEANSE DIETARY SUPPLEMENT	VEMMA NUTRITION COMPANY	NAUSEA, DIARRHOEA, ABDOMINAL PAIN, ABDOMINAL DISTENSION	VISITED AN ER, HOSPITALIZATION
107000	07/02/2013	VERVE ENERGY SUPPLEMENT	VEMMA NUTRITION COMPANY	VOMITING, NEPHROLITHIASIS, BODY TEMPERATURE INCREASED	VISITED AN ER, HOSPITALIZATION
167390	07/02/2013	VERVE ENERGY SUPPLEMENT	VEMMA NUTRITION COMPANY	VOMITING, NEPHROLITHIASIS, BODY TEMPERATURE INCREASED	VISITED AN ER, HOSPITALIZATION
171000	11/13/2013	VERVE	VEMMA NUTRITION COMPANY	HYPERTENSION, HEART RATE INCREASED	VISITED AN ER, HOSPITALIZATION
171923	11/13/2013	VERVE	VEMMA NUTRITION COMPANY	HYPERTENSION, HEART RATE INCREASED	VISITED AN ER, HOSPITALIZATION
172560	12/17/2013	VEMMA VERVE	VEMMA NUTRITION COMPANY	HEART RATE INCREASED	VISITED AN ER, HOSPITALIZATION
174102	02/20/2014	VEMMA NUT:RITION COMPANY VEMMA MANGOSTEEN PLUS	VEMMA NUTRITION COMPANY	ABDOMINAL DISCOMFORT, CHEST PAIN	VISITED AN ER, HOSPITALIZATION

Report #	RA_CAERS Created Date	Brand/Product Name	PRM_Firm Name	Symptoms	Outcomes
174183	02/24/2014	VEMMA NUTRITION COMPANY VEMMA MANGOSTEEN PLUS	VEMMA NUTRITION COMPANY	CHEST PAIN	VISITED AN ER, HOSPITALIZATION
174577	03/14/2014	VEMMA BOD-E CLEANSE	VEMMA NUTRITION COMPANY	URTICARIA, VOMITING, NAUSEA	HOSPITALIZATION
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	06/24/2013	VEMMA BOD-E CLEANSE DIETARY SUPPLEMENT	VEMMA NUTRITION COMPANY	NAUSEA, DIARRHOEA, ABDOMINAL PAIN, ABDOMINAL DISTENSION	VISITED AN ER, HOSPITALIZATION
166998	06/24/2013	VEMMA BOD-E CLEANSE DIETARY SUPPLEMENT	VEMMA NUTRITION COMPANY	NAUSEA, DIARRHOEA, ABDOMINAL PAIN, ABDOMINAL DISTENSION	VISITED AN ER, HOSPITALIZATION
407200	07/02/2013	VERVE ENERGY SUPPLEMENT	VEMMA NUTRITION COMPANY	VOMITING, NEPHROLITHIASIS, BODY TEMPERATURE INCREASED	VISITED AN ER, HOSPITALIZATION
167390	07/02/2013	VERVE ENERGY SUPPLEMENT	VEMMA NUTRITION COMPANY	VOMITING, NEPHROLITHIASIS, BODY TEMPERATURE INCREASED	VISITED AN ER, HOSPITALIZATION
474000	11/13/2013	VERVE	VEMMA NUTRITION COMPANY	HYPERTENSION, HEART RATE INCREASED	VISITED AN ER, HOSPITALIZATION
171923	11/13/2013	VERVE	VEMMA NUTRITION COMPANY	HYPERTENSION, HEART RATE INCREASED	VISITED AN ER, HOSPITALIZATION
172560	12/17/2013	VEMMA VERVE	VEMMA NUTRITION COMPANY	HEART RATE INCREASED	VISITED AN ER, HOSPITALIZATION
174102	02/20/2014	VEMMA NUT:RITION COMPANY VEMMA MANGOSTEEN PLUS	VEMMA NUTRITION COMPANY	ABDOMINAL DISCOMFORT, CHEST PAIN	VISITED AN ER, HOSPITALIZATION

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174577	03/14/2014	VEMMA BOD-E CLEANSE	VEMMA NUTRITION COMPANY	URTICARIA, VOMITING, NAUSEA	HOSPITALIZATION
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