FOI 15-5027

CAERS Reports Allegedly Related to Thrive Products (Le-Vel)

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 #	Received Date	Brand/Product Name	PRM_Firm Name	Symptoms	Outcomes
[redacted]					
179679	9/29/14	LEVEL THRIVE	UNKNOWN	BLOOD PRESSURE INCREASED, ATRIAL FIBRILLATION	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
[redacted]					

Report #	Received Date	Brand/Product Name	PRM_Firm Name	Symptoms	Outcomes
180013	10/14/14	LE-VEL BRANDS, LLC LEVEL THRIVE M (FORMULATED FOR MEN)	LE-VEL BRANDS LLC		NONE
		LE-VEL BRANDS LLC LEVEL THRIVE MW. (PREMIUM LIFESTYE MIX)	LE-VEL BRANDS LLC		
		LE-VEL BRANDS LLC LEVEL THRIVE (PREMIUM LIFESTYE DFT) PATCH	LE-VEL BRANDS LLC		
		LE-VEL BRANDS, LLC LE-VEL THRIVE W (FORMULATED FOR WOMEN) CAPSULES	LE-VEL BRANDS LLC		
180167	10/20/14	LE-VEL ACTIVATE	LE-VEL BRANDS LLC	HEADACHE, BLOOD PRESSURE ABNORMAL, BLOOD PRESSURE INCREASED, DEPRESSED MOOD, HYPERHIDROSIS, EUPHORIC MOOD, PAIN	NON-SERIOUS INJURIES/ ILLNESS
		LEVEL THRIVE FORMULATED FOR MEN & WOMEN	LE-VEL BRANDS LLC		
		LEVEL THRIVE M FORMULATED FOR MEN	LE-VEL BRANDS LLC		
		LE-VEL THRIVE - PREMIUM LIFESTYLE DFT	LE-VEL BRANDS LLC		
		LEVEL THRIVE W FORMULATED FOR WOMEN	LE-VEL BRANDS LLC		
180670	11/7/14	LE-VEL THRIVE	LE-VEL BRANDS LLC	DIZZINESS, DEHYDRATION, NAUSEA, HEADACHE, HEART RATE INCREASED, WITHDRAWAL SYNDROME	NON-SERIOUS INJURIES/ ILLNESS
[redacted]					
180706	11/7/14	LE-VEL THRIVE	LE-VEL BRANDS LLC	HEADACHE, HEART RATE INCREASED, JOINT SWELLING, WITHDRAWAL SYNDROME	NON-SERIOUS INJURIES/ ILLNESS

Report #	Received Date	Brand/Product Name	PRM_Firm Name	Symptoms	Outcomes
180707	11/7/14	LE- VEL THRIVE	LE-VEL BRANDS LLC	BLOOD PRESSURE INCREASED, ANXIETY, HEADACHE, ABDOMINAL DISCOMFORT, HYPERTENSION	NON-SERIOUS INJURIES/ ILLNESS
180716	11/10/14	LE-VEL THRIVE	LE-VEL BRANDS, LLC	HEART RATE INCREASED	NON-SERIOUS INJURIES/ ILLNESS
181137	12/1/14	LE-VEL THRIVE	LE-VEL BRANDS, LLC	FEELING JITTERY, ANXIETY, HEADACHE, ABDOMINAL DISCOMFORT, HEART RATE INCREASED	NON-SERIOUS INJURIES/ ILLNESS
185496	4/28/15	THRIVE LE-VEL	LE-VEL BRANDS, LLC	TREMOR, CENTRAL NERVOUS SYSTEM STIMULATION, BLOOD PRESSURE INCREASED, HYPERHIDROSIS	NON-SERIOUS INJURIES/ ILLNESS
186514	5/31/15	LE-VEL THRIVE	LE-VEL BRANDS LLC	BREATH SOUNDS ABNORMAL, ATRIAL FIBRILLATION	VISITED AN ER
186996	9/26/13	THRIVE FORMULATED FOR WOMEN PREMIUM LIFESTYLE MIX	UNKNOWN		NONE
187151	6/19/15	THRIVE LEVEL	LE-VEL BRANDS, LLC		OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
187152	6/19/15	THRIVE LE-VEL	LE-VEL BRANDS, LLC	BLOOD PRESSURE INCREASED	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
187474	6/28/15	THRIVE PREMIUM LIFESTYLE MIX	NOT AVAILABLE		NON-SERIOUS INJURIES/ ILLNESS
187499	6/29/15	LE-VEL THRIVE	DUN&BRADSTREET LAVELLE CO	ABDOMINAL PAIN, DIARRHOEA, SECRETION DISCHARGE, HAEMATOCHEZIA	NON-SERIOUS INJURIES/ ILLNESS
187570	6/30/15	THRIVE PREMIUM LIFESTYLE DFT WOMEN'S TONE PACK - PATCH	LE-VEL BRANDS, LLC	PALPITATIONS, DYSPNOEA, ATRIAL FIBRILLATION, CHEST PAIN, DIZZINESS	HOSPITALIZATION
		THRIVE PREMIUM LIFESTYLE DFT WOMEN'S TONE PACK - PILLS	LE-VEL BRANDS LLC		
		THRIVE PREMIUM LIFESTYLE DFT WOMEN'S TONE PACK - SHAKES	LE-VEL BRANDS LLC		
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