

FOI 14-6210
CAERS Reports Allegedly Related to Cancer in Multiple Cosmetics
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	PRI_FDA Industry Code	PI_One Row Ingredients	Symptoms	Outcomes
83239	01/20/2006	OPI NAIL POLISH	53	UNKNOWN	BREAST CANCER	NON-SERIOUS INJURIES/ ILLNESS
84265	03/09/2006	ESTEE LAUDER DOUBLE MATTING, PEBBLE COLOR	53	UNKNOWN	PAIN, SCAR, SKIN CANCER, HYPERPLASIA, DYSPLASIA, RASH PAPULAR, SKIN CANCER, INFECTION, LYMPHADENECTOMY, MYELOID METAPLASIA, MYELOID METAPLASIA, DEPRESSED LEVEL OF CONSCIOUSNESS	VISITED A HEALTH CARE PROVIDER, DISABILITY
84269	03/09/2006	ESTEE LAUDER DOUBLE MATTING, PEBBLE COLOR	53	UNKNOWN	SKIN CANCER, DYSPLASIA, SKIN GRAFT, HYPERPLASIA, ACNE	DISABILITY, VISITED A HEALTH CARE PROVIDER
144084	10/03/2011	COPPOLA BRAZILIAN KERATIN	53	FORMALDEHYDE	LYMPHADENOPATHY, HYPOTRICHOSIS, THYROID CANCER, MEMORY IMPAIRMENT, ABORTION SPONTANEOUS, FATIGUE	VISITED A HEALTH CARE PROVIDER
155918	08/29/2012	LUBRIDERM DAILY MOISTURE LOTION FOR NORMAL TO DRY LOTION	53	MISSING LABEL	BLADDER CANCER	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
162802	02/28/2013	ACTIVE SERUM	53	UNKNOWN	HYPOTRICHOSIS, SKIN CANCER	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), LIFE THREATENING
	02/28/2013	HAIR COMPLEX	53	UNKNOWN		

Report #	RA_CAERS Created Date	Brand/Product Name	PRI_FDA Industry Code	PI_One Row Ingredients	Symptoms	Outcomes
165492	05/14/2013	LUBRIDERM UNSPECIFIED (DERMATOLOGICAL PRODUCTS) LOTION	53	UNKNOWN	OVARIAN CANCER	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
170684	10/01/2013	COCO'S EXTRA STRENGTH BRAZILIAN	53	UNKNOWN	BREAST CANCER	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
172659	12/19/2013	MYSTIC TAN SPRAY ON TAN - DARK COLOR	53	DIHYDROXYACTONE	LUNG NEOPLASM MALIGNANT, BRAIN CANCER METASTATIC, BRONCHIOLOALVEOLAR CARCINOMA, HEPATIC NEOPLASM MALIGNANT	DEATH, VISITED A HEALTH CARE PROVIDER, HOSPITALIZATION
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