

Dockets Management Branch
The Food and Drug Administration
Department of Health & Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Date: April 12, 2000

Re: 99P-1340/CP 1 — Petition to Have *Eternity eau de parfum* declared "misbranded" ^{5708 '00 OCT -4} A9:58

Dear Sir or Madam:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's *Eternity eau de parfum* declared "misbranded." I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning — The safety of this product has not been determined."

As the petition shows, *Eternity* contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as *Eternity* so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers. When I am exposed to **fragrance products** I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> anaphylaxis/shock | <input type="checkbox"/> double vision | <input checked="" type="checkbox"/> incoherence | <input checked="" type="checkbox"/> nausea |
| <input checked="" type="checkbox"/> anxiety, restlessness | <input type="checkbox"/> ear pain | <input type="checkbox"/> incontinence | <input type="checkbox"/> nose bleeds |
| <input type="checkbox"/> asthma | <input type="checkbox"/> eczema | <input checked="" type="checkbox"/> irritability | <input type="checkbox"/> rashes |
| <input checked="" type="checkbox"/> breathing difficulty | <input type="checkbox"/> eyes, watery or dry | <input checked="" type="checkbox"/> joint aches | <input type="checkbox"/> seizures |
| <input type="checkbox"/> bronchitis | <input checked="" type="checkbox"/> fatigue | <input type="checkbox"/> laryngitis | <input checked="" type="checkbox"/> short-term mem. loss |
| <input checked="" type="checkbox"/> can't concentrate | <input checked="" type="checkbox"/> flushing | <input checked="" type="checkbox"/> lethargy | <input checked="" type="checkbox"/> sinusitis |
| <input checked="" type="checkbox"/> coughing | <input type="checkbox"/> headaches | <input checked="" type="checkbox"/> lymph nodes swell | <input checked="" type="checkbox"/> sneezing |
| <input checked="" type="checkbox"/> depression | <input checked="" type="checkbox"/> heart beat irregularity | <input checked="" type="checkbox"/> mood swings | <input type="checkbox"/> sores, skin/mouth |
| <input checked="" type="checkbox"/> disorientation | <input type="checkbox"/> hives | <input checked="" type="checkbox"/> muscle pain/weakness | <input checked="" type="checkbox"/> swallowing difficulty |
| <input checked="" type="checkbox"/> dizziness | <input checked="" type="checkbox"/> hypertension | <input checked="" type="checkbox"/> nasal congestion | <input type="checkbox"/> tinnitus |

other: extremely rapid heart beat, over 250 beats per minute at rest. Faint, paralysis and muscle discoordination. Hyperactive Airway Syndrome... see over 700 articles on Internet/Respiratory

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you. All toxic chemicals and solvents should be illegal to put in contact with people, animals, plants, AIR, WATER, EARTH OR FIRE. This is about alot more than one product. Just like tobacco smoke, 2nd hand fumes of toxics are an invasion of our rights to clean air space.. and a health hazard to the user as well.

Meaghan Simpson
your name

P.O. Box 1822, Redway, CA 95560
address; city/st/zip

C 669

99P-1340

Newsletters and everyone who feels people have a right to know, please copy, share, tell your friends and WRITE the FDA... today!

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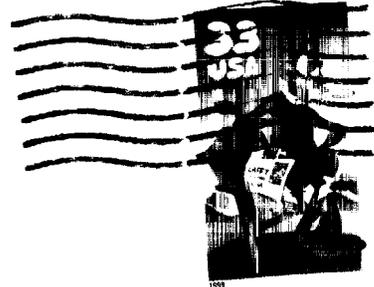
Dear Person who must become concerned:

As a person who works as health care professional in advocacy and caregiving for people with injuries and sensitivities from toxic chemicals and solvents, and numerous other maladies directly related to environmental illnesses with same source of cause...

It is of importance to say more about the entire "fragrance" marketplace and the overdue redress/address of safety codes/guidelines... for labelling, ingredients listing, marketing slogans and the citizens rights to completely full disclosure... EVERYTHING even what ingredients containers are made from and what products are used to sterilize them. Standards for products that are applied topically should be as safe as our best certified organic food standards. Our bodies absorb ever so swiftly through the skin or via the "fragrance" in the air. It shall become

unlawful to wear these poisons or invade the air space in public places. A lot like public tobacco smoking, poisonous "fragrances" are more and more NOT ALLOWED. Even Independent Living Centers and Dept. of Vocational Rehabilitation are "Fragrance Free" Zones. This is a fact because so many people are violently or acutely effected by fumes from synthetic scents. It is a crime that the safety code of the SKULL and Crossbones was rather silently replaced by under protective codes of DANGER, WARNING and CAUTION on product containers. Most people need a crash course from POISON CONTROL HOTLINE educators to see how dangerous and critical the crisis is. People need protective rights/education about common air space. People by the millions are suffering serious life threatening maladies due to these toxics and many others. Perfume is originally a French word which means simply Pure... Fume... meant to benefit the health like the holy anointing oils and perfumes mentioned in the Bible so many times. We are the leaders... for CLEAN AIR, WATER, etc. Please STOP ~~and~~ releasing UNSAFE products upon the ignorance of the consumer. CLEAN UP ALL REGULATIONS world wide. Every moment some body is getting real sick... see US Health Services studies! Respectfully The Mending Wheel and Meaghan Simpson

Mending Wheel c/o M. Simpson
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