

Date: 5/23/00

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

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MAY 26 AM 10:20

Re: Docket Number: 99P-1340/CP 1
Petition the FDA Have Calvin Klein's *Eternity eau de*
***parfum* declared "misbranded"**

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 specifically 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:

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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, such as "Eternity," I have seizures, become nauseous, dizzy, my eyes itch, my skin itches, and I often wind up with a headache for quite a while, although getting away from the fragrance helps considerably. The problem comes when I have to work with other people who insist upon wearing fragrances. I need to work to be able to live on my own, and yet it is sometimes impossible to work because of the physical symptoms I encounter, many of which are listed below. Any of these symptoms is a possibility, and I never know which fragrance or chemical in a cleaning solution or the like will set off these reactions.

<u>X</u> anxiety, restlessness	<u>X</u> itchy eyes	<u>X</u> nausea	<u>X</u> irritability
<u>X</u> breathing difficulty	<u>X</u> dry, burning eyes	<u>X</u> rashes	<u>X</u> seizures
<u>X</u> can't concentrate	<u>X</u> flushing	<u>X</u> lethargy	<u>X</u> sinusitis
<u>X</u> coughing	<u>X</u> headaches		<u>X</u> sneezing
<u>X</u> depression		<u>X</u> mood swings	
<u>X</u> disorientation	<u>X</u> hives		
<u>X</u> dizziness	<u>X</u> fatigue	<u>X</u> nasal congestion	<u>X</u> short-term memory loss

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.

Sincerely,



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