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Angel Parfum Petition Moves to Second Stage of FDA Review.

Update on Petition to Declare Angel Parfum a Drug and other FDA issues regarding Clarins, Paris.

FOR IMMEDIATE RELEASE

PR Log (Press Release) – Jul 23, 2008 – The National Toxic Encephalopathy Foundation (NTEF) who in November of 2007, filed their petition to have Angel Parfum Declared a Drug is moving through the investigative process at the Food and Drug Administration (FDA).

In a telephone call with the FDA, the NTEF was informed that the petition is actively being worked on by the FDA and currently in the hands of a second scientist for further review. "We are thrilled that the FDA is giving our petition the attention and scientific scrutiny that we did in complying the science behind it," said Angel De Fazio, President of the NTEF.

"We are anticipating a determination by the end of the year predicated on the procedures that were delineated to us by the FDA. We, of course, would have liked a determination sooner, but, with the voluminous references to federal code violations and detrimental health effects, we appreciate the thoroughness that the FDA is giving to our petition. This first petition's decision we are optimistic will expedite the second petition that was submitted in January 2008, citing many of the same code violations and detrimental health effects," said De Fazio.

The FDA did confirm that they are actively looking into the marketing claims made by Clarins for their Expertise 3P effectiveness. As Clarins was taken to task in August of 2007, by the Advertising Standards Authority in the United Kingdom for the same issues that the NTEF addressed.

The current product being submitted for drug versus cosmetic claims is Clarins Double Serum Generation 6. In 1987, the FDA warned Clarins that Double Serum violated cosmetic claims as this product was in fact making drug claims. "FDA's Newark district office investigator Jacques Maravic looked on last October [1989] while 7,500 ½ -ounce bottles of Clarins Double-Serum Multi-Regenerant Anti-Aging Total Skin Supplement and 94,000 accompanying pieces of literature in English and Spanish were loaded into a 40-foot-long container. The goods valued at nearly 100,000, were on their way to being shipped back to the French manufacturer from whence they had come. In any language, it spelled fraud." [1]

Now, years later, with four significant updates, Clarins is reintroducing this product into the retail stores worldwide. "From what we have seen and read, Clarins is still making drug versus cosmetic claims and our formal complaint will be referencing all of our findings," said De Fazio.

[1] Serum shipped out for not shaping up. FDA Consumer, March 1990. Dixie Farley, Judy Folkenberg, Marian Segal.

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