

Clarins Expertise 3P is a Drug According To FDA.

By National Toxic Encephalopathy Foundation

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Clarins Expertise 3P product touting effectiveness against artificial electro-magnetic radiation is not a cosmetic but is viewed as making drug claims.

The National Toxic Encephalopathy Foundation (NTEF) is pleased to announce that the Food and Drug Administration (FDA) has concurred that Clarins Expertise 3P (EP3) is a drug, not a cosmetic as advertised.

In February, the NTEF notified the FDA that Clarins EP3 was making drug versus cosmetics claims and requested an investigation into these allegations. As previously stated: "We are now requesting that the FDA verify the claims made by Clarins, in vitro testing versus in vivo testing, along with compliance, since this product is a new drug under section 201(p) of the FDCA, 21 U.S.C. subsection 321 (p), because it is not generally recognized by qualified scientific experts as "effective" for its intended use."

On October 1, 2008, the NTEF received the following notification from Patricia A. Hansen, Ph.D. Sr. Advisor for Science and Policy at the FDA:

"The Office of Cosmetics and Colors has reviewed the information at the U.S. website, where products may also be purchased, and consulted with others in the Agency. We are of the opinion that the claims made are drug claims. We have referred the matter to the office that handles these issues, FDA's Office of Non-Prescription Drug Products in the Center for Drug Evaluation and Research (CDER)."

"We couldn't be happier with the FDA's determination regarding EP3", said Angel De Fazio, President of the NTEF. "Cosmetic companies have been skirting the drug versus cosmetics claims for too long. It is hoped that as a result of this action, cosmetic companies, such as Clarins, will stop their deceptive advertising. It is expected that in the future they will be forced to submit new drug applications for their products when making medical claims".

"I extol the opinion of the FDA's findings regarding EP3 and am confident that they will be of the same mind regarding the two dozen plus other drug versus cosmetic claims that we have submitted. As we will be just as aggressive in having those also being re-classified", said Dr. Jack D. Thrasher, Ph.D., Toxicologist, Immuno-toxicologist, Fetal-toxicologist and technical director for the NTEF. "Clarins has pushed both the limit of believability and cosmetic references regarding this product. This is not the first time that the FDA has taken Clarins to task for drug versus cosmetic claims and we are highly confident that this will not be the last."

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The NTEF is a watchdog environmental group seeking to notify the public of the hazards inherent in consumer products that have not been fully tested for safety.

Along with having cosmetics that are making medical claims reclassified as a drug and requesting FDA regulatory requirements regarding their safety, effectiveness, etc., be implemented.

The Foundation's main object is to educate the public on the inherent dangers to the brain associated with the chemicals in fragrances, air fresheners, pesticides, various other consumer products that they have been lead to believe are fully tested for safety. For every chemically based product, there is at least one safer

alternative that has been proven just as effective.

Category	Government, Legal, Beauty
Tags	clarins expertise 3p, fda, drug, cosmetic, ntef, non-prescription drug application, drug vs cosmetic claim
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