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## Serum shipped out for not shaping up

FDA Consumer, March, 1990 by Dixie Farley, Judy Folkenberg, Marian Segal

FDA's Newark district office investigator Jacques Maravic looked on last October while 7,500 1/2-ounce bottles of Clarin's 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.

A brochure called "Reference Guide for a Youthful Face, a Firm Bust, a Toned Body" touted the product as the only formula in existence which successfully combines the 18 highly concentrated 'anti-aging' ingredients needed to effectively combat the appearance of the aging process of the skin."

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As FDA wrote in a May 1, 1987, regulatory letter to the distributor, Clarins, Inc. of New York, the claims suggest that "the articles are intended to affect the structure and function of the human body, and that the products are adequate and effective for such uses as preventing the effects of the aging process, rebuilding the epidermis, refining the shape of the face, stimulating cell renewal and other claims." According to FDA, these claims classify the product as a drug.

Clarins never obtained FDA approval of Double-Serum as a safe and effective anti-aging

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agent. (Nor has anyone else.) The agency informed the firm that sale of the product with unsubstantiated drug claims was illegal under the Food, Drug, and Cosmetic Act and warned the firm to correct the violation. On June 30, Clarins' marketing manager wrote to FDA's New York district office, stating that the labeling changes would be complete by Aug. 15, 1988. But they weren't.

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Inspecting the firm's Oakland, N.J., warehouse in October 1988, Newark district investigators found that Double-Serum labels continued to include drug claims. In addition, the brochures were found at department store counters in Washington, D.C., and New York City in December 1988 and March 1989. During a follow-up inspection in May, investigators found 1,560 units of Double-Serum at the Oakland warehouse with 87,000 pieces of literature making false claims for the product. On July 20, at FDA's request, the materials were seized, and in September, Clarins entered into a consent decree, agreeing to export the materials back to the supplier, Clarins, S.A., in Paris, France.

-This small sample of reports from the field was prepared by Dixie Farley, Judy Folkenberg, and Marian Segal.

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