

TO THE EDITOR:

We found a recent 2-part series in the January and February 2010 issues of *Cosmetic Dermatology*[®] by Farris and Rendon^{1,2} to be well written, but wish to respectfully point out a recurring error and omission concerning an available US Food and Drug Administration (FDA)–approved formulation for use in the mitigation of fine wrinkles.

Part 1 of the series stated: “In the United States, tretinoin 0.02% cream is the only tretinoin formulation approved for the use in the mitigation of fine wrinkles associated with photodamage on the basis of significant benefit in randomized, double-blind, placebo-controlled trials.”¹ In fact a higher strength of tretinoin, tretinoin emollient cream 0.05%, is available to patients and was approved by the FDA in 2005 for use in the mitigation of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin.^{3,4} This tretinoin emollient cream 0.05% (now branded as Refissa) was proven to be bioequivalent to tretinoin emollient cream 0.05% (Renova) in a randomized, double-blind, placebo-controlled clinical trial that included 420 participants aged 40 to 75 years, and improved fine wrinkles in 71% and mottled hyperpigmentation in 83% of participants.⁵ Shortly after tretinoin emollient cream 0.05% was approved by the FDA in 2005, tretinoin emollient cream 0.05% (Renova) was removed from the market while tretinoin cream 0.02% (Renova) continued to be promoted.

Over the last year, the tretinoin emollient cream 0.05% (Refissa)

formulation has been improved by removing the fragrance and quaternium-15 to reduce the potential for allergenicity and was branded as Refissa cream 0.05%.⁴

In part 2 of the series a similar error and omission occurs. The abstract stated: “Among the tretinoin formulations available in the United States, only Renova (tretinoin 0.02%) is indicated for use in photodamage.”² Additionally, in Table 1, which listed topical retinoid agents available in the United States,² there is an apparent omission, as neither tretinoin emollient cream 0.05% (Refissa) nor generic tretinoin emollient cream 0.05% are mentioned. As noted, tretinoin emollient cream 0.05% (Refissa) is approved for use in the mitigation of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin. Tretinoin cream 0.02% (Renova) is only approved for the mitigation of fine facial wrinkles. The package insert states: “Renova 0.02% has Not Demonstrated A Mitigating Effect on . . . mottled hyperpigmentation.”⁶

As Dr. Weinkle pointed out at the January 2010 South Beach Aesthetic Dermatology Symposium in her presentation *Tretinoin: The Super Cosmeceutical*, “Refissa is the only topical retinoid on the market that has all 3 labeled indications: fine wrinkles, hyperpigmentation, and tactile roughness.”⁷

Sincerely,
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Dr. Spear is President, Spear Pharmaceuticals. Dr. Weinkle reports no conflict of interest in relation to this article.

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AUTHORS RESPONSE

The 2-part series on topical retinoids for the treatment of nonmalignant photodamage in clinical practice published in the January and February 2010 issues of *Cosmetic Dermatology*[®] indicated that tretinoin cream 0.02% (Renova) is the only tretinoin formulation approved in the United States for

the use in the mitigation of fine facial wrinkles associated with photodamage on the basis of significant benefit in randomized, double-blind, placebo-controlled trials.^{1,2} Although generic tretinoin emollient cream 0.05% was approved by the US Food and Drug Administration for use in 2005, at the time of the initial manuscript development, tretinoin cream 0.02% (Renova) was the only branded tretinoin formulation approved for the mitigation of photodamage. Tretinoin emollient

cream 0.05% (Refissa) subsequently was approved in 2009. We apologize for this oversight.

Sincerely,
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Dr. Farris is on the advisory board of Neutrogena Corporation, is a consultant

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