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Sept 12, 2012

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Cc:
Steven Rosen, Senior University Counsel
Stanford University
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Dear Sirs:

We note with interest FDA's 15-day warning letter, issued 9-7-2012 to L'Oreal in the context of unsubstantiated medical claims made for anti-aging cosmetics products sold by Lancome in the US. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm318809.htm>

This letter raises to your attention comparable but far more extreme unsubstantiated medical claims made by the "AgeLOC" flagship brand applied to at least 11 of Nu Skin's cosmetics, dietary supplement, and electrical device products.

It is our opinion that the abuses in market practices of Nu Skin are of far more concern than those of Lancome, for the following reasons:

- 1) The extreme nature of the claims themselves, including extensive marketing communications based upon the following themes, especially as describing the "AgeLOC" brand:

"Resets Youth Gene Clusters"

"Modulates genetic expression"

"Fountain of Youth – we have found out how to unlock the secret of youth by resetting Youth Gene Clusters"

"Algorithm that identifies groups of genes [arSuperMarkers] that play a central role in the aging process"

"products that ... work at the genetic level"

- 2) **Products sold by 170,000 independent representatives in the "Americas" (including US, Canada and Latin America – no specific US distributors numbers are disclosed) and 860,000 distributors worldwide. No doubt a vast number of these distributors and their customers are U.S. based .** This creates a severe enforcement problem in terms of the specific training these representatives receive, and the specific claims they may be instructed to make to potential customers. There are numerous examples of these claims being made in marketing and support materials provided to these representatives.

(Just 2 of numerous examples:)

<https://sites.google.com/site/nugenteam/prospecting>

<http://geneticantiaging.org/>

- 3) **Association with noted prestigious research institutions**

Nu Skin prominently promotes itself and repeatedly associates its products with the names of Stanford University and Purdue University in conjunction with its marketing claims for "AgeLOC". There are (literally hundreds of statements on Nu Skin's various websites and PR stating that Stanford is in a "partnership" and/or "collaboration" with Nu Skin regarding the genetic sources of aging and their products efficacy in treating aging "at its source".)

(Again, just a small sampling of hundreds of instances:)

http://www.ageloc.com/ageloc/en-US/ageloc_science/scientific_foundation.html

<http://www.defineyourage.com/HealthCarePros.html>

https://www.nuskin.com/content/nuskin/en_SG/products/anti-aging_opportunity/science/worldwide_collaboration.html

http://ir.nuskin.com/phoenix.zhtml?c=103888&p=irol-newsArticle_print&ID=1348761&highlight=

<http://www.nuskin.com/microsites/liveandlookyoung/au-en/solution.html>

https://www.nuskin.com/content/nuskin/en_NZ/products/anti-aging/sources_of_aging/jcr_content/bottomright/download_0/file.res/ageLOCScienceBrochureJan2010.pdf

4) **Product already impounded**

FDA records indicate that at least two shipments of Nu Skin electrical devices have been impounded at ports of entry, in conjunction with FDA determination of whether they should be classified as "medical devices". Since these products are identified as "AgeLOC", there is no doubt that the marketing claims of the "AgeLOC" brand attach to them.

http://www.accessdata.fda.gov/scripts/importrefusals/ir_detail.cfm?EntryId=112-8601643-5&DocId=1&LineId=1&SfxId=A

and

http://www.accessdata.fda.gov/scripts/importrefusals/ir_detail.cfm?EntryId=112-8601643-5&DocId=1&LineId=1&SfxId=B

Similar products appear to be manufactured and sold by Nu Skin in the US and worldwide today.

Conclusion

Clarity is urgently needed by all parties, including those participating in legitimate gene therapy research and development, the entire cosmetics and dietary supplement products industry, Nu Skin's distributors and customers, and the public market for investments in the wide range of companies whose revenues and profits are impacted by your regulatory scope.

We understand FDA's budgetary constraints require selection of issues and companies affected, but we hope the scope and impacts of the issues presented above is broad enough to warrant immediate clarity from your agency.

Yours truly,

Andrew Left, Editor
Citron Research