Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

WARNING LETTER

SEP 7 2012

VIA CERTIFIED MAIL

Mr. Serge Jureidini
President
Lancôme USA
575 Fifth Avenue
New York, NY 10017

Re: 273596

Dear Mr. Jureidini:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address http://www.lancome-usa.com in August 2012. Based on this review, your products Génifique Youth Activating Concentrate, Genefique Eye Youth Activating Eye Concentrate, Genefique Cream Serum Youth Activating Cream Serum, Génifique Repair Youth Activating Night Cream, Absolue Precious Cells Advanced Regenerating and Reconstructing Cream SPF 15 Sunscreen, Absolue Eye Precious Cells Advanced Regenerating and Reconstructing Eye Cream, Absolue Night Precious Cells Advanced Regenerating and Reconstructing Night Cream, and Rénergie Microlift Eye R.A.R.E.™ Intense Repositioning Eye Lifter appear to be promoted for uses that cause these products to be drugs under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(C)]. The claims on your web site indicate that these products are intended to affect the structure or any function of the human body, rendering them drugs under the Act. The marketing of these products with these claims evidencing these intended uses violates the Act.

Examples of some of the claims observed on your web site include:

Génifique Youth Activating Concentrate, Génifique Eye Youth Activating Eye Concentrate, and Génifique Cream Serum Youth Activating Cream Serum

- "[B]oosts the activity of genes and stimulates the production of youth proteins."

Génifique Repair Youth Activating Night Cream

- "[B]oosts the activity of genes."

Absolue Precious Cells Advanced Regenerating and Reconstructing Cream SPF 15 Sunscreen

- "A powerful combination of unique ingredients – Reconstruction Complex and Pro-Xylane™, a patented scientific innovation-- has been shown to improve the condition around the stem cells and stimulate cell regeneration to reconstruct skin to a denser quality."
- "See significant deep wrinkle reduction in UV damaged skin, clinically proven."

Absolue Eye Precious Cells Advanced Regenerating and Reconstructing Eye Cream and Absolue Night Precious Cells Advanced Regenerating and Reconstructing Night Cream

- "A powerful combination of unique ingredients – Reconstruction Complex and Pro-Xylane™, a patented scientific innovation-- has been shown to improve the condition around the stem cells and stimulate cell regeneration to reconstruct skin to a denser quality."

Rénergie Microlift Eye R.A.R.E.™ Intense Repositioning Eye Lifter

- "Immediate lifting, lasting repositioning. Inspired by eye-lifting surgical techniques . . . helps recreate a younger, lifted look in the delicate eye area."
- "[U]nique R.A.R.E. oligopeptide helps to re-bundle collagen."

Your products are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505(a) of the Act (21 U.S.C. § 355(a)) a new drug may not be legally marketed in the U.S. without prior approval from FDA in the form of an approved New Drug Application (NDA). A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

This letter is not an all-inclusive statement of violations associated with your products or their labeling, and we have not attempted to list here all of the products that are promoted on your website for intended uses that cause them to be drugs. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling for your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.

We request that you take prompt action to correct all violations associated with your products, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Please direct your written reply to Rob Genzel, Jr., Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement(HFS-608), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,
/S/
Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety and Applied Nutrition

Department of Health and Human Services

Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

NOV 19 2012

Paul M. Hyman
Law Offices of Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, DC 20005

Re: 273596

Dear Mr. Hyman:

The Food and Drug Administration has completed an evaluation of your corrective actions in response to our Warning Letter dated September 7, 2012. Based on our review, it appears that you have addressed the violations contained in this Warning Letter. Future FDA assessments and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent review of your web sites or through other means.

Sincerely,

/S/

Kathleen M. Lewis, J.D.
Team Leader
Labeling and Dietary Supplement
Compliance Team
Center for Food Safety
and Applied Nutrition

Cc:
Serge Jureidini
President
Lancome USA
575 Fifth Avenue
New York, NY 10017

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

FEB 12, 2015

WARNING LETTER

VIA OVERNIGHT DELIVERY

Brigitte Liberman, President Active Cosmetics Division
L'Oréal USA
575 Fifth Avenue
New York, NY 10017

Re: CMS # 440851

Dear Ms. Brigitte Liberman:

This letter is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address http://www.laroche-posay.us in December 2014. Based on this review, you take orders there for your products "Rosalic AR Intense" and "Mela-D Pigment Control," which appear to be promoted for uses that cause the products to be drugs under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(C)]. The claims on your website indicate that the products are intended for use in the cure, mitigation, treatment, or prevention of disease and/or are intended to affect the structure or any function of the human body, rendering them drugs under the Act. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the claims on the website www.laroche-posay.us, that provide evidence that your products are intended for use as drugs include:

Rosaliac AR Intense:

- "Localized Redness Intensive Serum"
- "RECOMMENDED FOR: Redness-prone skin, experiencing overall redness, flushing and sensations of discomfort"
- "Reduces visible redness and sensations of discomfort"
- "[F]ormula combining 3 effective ingredients to help reduce redness with a long lasting efficacy"
- "I have rosaceaon my neck when I get warm or under stress. This product really works to keep it under control!!!"
- "I have broken capillaries and generalized redness on several areas of my face. I was told laser treatment was the only fix. Then...the miracle of Rosalic AR!"
- "With powerful Ambophenol [0.5%] to visibly reduce redness"

Mela-D Pigment Control:

- "Concentrated Dark Spot Correcting Serum"
- "Use to treat dark spots and discolorations"
- "Recommended For: Hyperpigmentation and Dark Spots"
- "With 2% Kojic Acid to visibly reduce the intensity of dark spots"

Your "Rosalic AR Intense" and "Mela-D Pigment Control" products are not generally recognized as safe and effective for the above-referenced uses and, therefore, these products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the Act [21 U.S.C. § 355(a)]; see also section 301(d) of the Act [21 U.S.C. § 331(d)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

Furthermore, your "Rosaliac AR Intense" product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus, this drug is misbranded within the meaning of section 502(f)(1) of the Act, in that its labeling fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)]. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

This letter is not an all-inclusive statement of violations associated with your products or their labeling, and we have not attempted to list here all of the products that are promoted on your website for intended uses that cause them to be drugs. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling for your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.

We request that you take prompt action to correct the violations cited in this letter. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be implemented.

You should direct your written reply to Dehlia Young, Compliance Officer, Division of Enforcement (HFS-608), Office of Compliance, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy, College Park, MD 20740. If you have any questions regarding this letter, you may contact Ms. Young via email at dehlia.young@fda.hhs.gov.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

U.S. FOOD & DRUG ADMINISTRATION

5001 Campus Drive
College Park, MD 20740

AUG 1, 2017

Brigitte Liberman,
President Active Cosmetics Division
L'Oreal USA
575 Fifth Avenue
New York, NY 10017

Dear Ms. Liberman:

The Food and Drug Administration has completed an evaluation of your firm's corrective actions in response to our Warning Letter #440851 issued February 12, 2015. Based on our evaluation, it appears that you have addressed the violation(s) contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

/S/

Latasha A. Robinson
Branch Chief
Dietary Supplements & Labeling Assessment Branch
Office of Compliance
Center for Food Safety
and Applied Nutrition