Health Canada Santé Canada

Regulatory Operations and Enforcement Branch
Health Product Compliance West
400-4595 Canada Way
Burnaby, BC V5G 1J9

January 06, 2021

College of Optometrists of British Columbia
906-938 Howe Street
Vancouver, BC V6Z 1N9

**Sent via e-mail to:** college@optometrybc.ca

**RE: Regener-Eyes Ophthalmic Solution Professional Strength and Regener-Eyes Ophthalmic Solution Lite**

Dear Registrar**,**

This letter is to advise you of an email titled "Regener-Eyes® Ophthalmic Solution Available for Use in Canada" that may have been sent to your optometrists on December 10, 2020. The email was sent by Heidi Hart Pukas at heidipukas@mydryeyes.org from My Dry Eyes. This letter contains false and misleading information about the availability and use of Regener-Eyes Ophthalmic Solution Professional Strength and Regener-Eyes Ophthalmic Solution Lite ("Regener-Eyes") in Canada. You are being informed of Health Canada's position with Regener-Eyes so your optometrists are in compliance with the ***Food and Drugs Act*** (FDA) and the ***Food and Drug Regulations*** (FDR).

Regener-Eyes is classified as an unlicensed biologic drug in Canada. The product claims to contain human placenta materials. Health Canada has not authorized any health products containing human placenta in Canada and they may pose serious health risks. To be legally sold in Canada, all drugs must have a product license, known as a Drug Identification Number (DIN). Drugs with valid DINs have been assessed for safety and efficacy, labelling and instructions for use. A drug product sold in Canada without a DIN is non-compliant with Canadian law.

**Section C.01.014(1) of the *FDR*** states:

> *"No manufacturer shall sell a drug in dosage form unless a drug identification number has been assigned for that drug and the assignment of the number has not been cancelled under section C.01.014.6."*

**Discrepancies in Email**

In the email from My Dry Eyes, it states "there has never been any safety recall of this product". In September and October 2020, Health Canada posted a recall and public advisory for Regener-Eyes. Healthcare professionals should stop prescribing and/or dispensing Regener-Eyes immediately.

In the email, it states "individual patients are permitted to import a 90-day supply for personal use for a single course of treatment. The patient will need a prescription from a Canadian Eye Care Professional." In Health Canada's Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations (GUI-0084), under Human Drugs > Personal Use Importations > Schedule D drugs (drugs derived from Human, Animal or microbial sources, such as

insulin and blood based products), it states:

> *"Individuals are permitted to import a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of an Over the Counter Drug.*
>
> *The drug must be for the individual's own personal use or for the use of a person for whom they are responsible and with whom they are travelling.*
>
> *The drug must be shipped/carried in one of the following:*
>
> - *Hospital or pharmacy dispensed packaging;*
> - *Original retail packaging; or*
> - *have the original label affixed to it which clearly indicates what the health product is and what it contains."*

Health care professionals are not permitted to import drugs on behalf of their patients as this is considered a commercial importation. It is also not permitted for health care professionals to advertise an unlicensed drug in Canada. Healthcare professionals should not be prescribing Regener-Eyes as it is an unlicensed drug.

**Section 9(1) of the *FDA***, states:

> "*No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.*"

Health Canada uses a collection of compliance and enforcement tools to monitor and verify that regulated parties comply with the requirements of the Food and Drugs Act and its associated Regulations. When non-compliance is brought to the attention of a regulated party, it is the regulated party's responsibility to take timely and appropriate action to come into compliance with legislative and regulatory requirements. We invite you to review Health Canada's Compliance and Enforcement Policy (POL-0001).

Please contact me if you have any questions.

Sincerely,

Amanda Wong
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Health Product Compliance West
Regulatory Operations and Enforcement Branch
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