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ABB Optical Group  
12301 NW 39th St  
Coral Springs, FL 33065

Dry Eye Rescue LLC  
1200 S Rogers Circle Ste 16  
Boca Raton, FL 33487

May 1, 2023

**OPEN LETTER TO ABB OPTICAL AND DRY EYE RESCUE**

*re: Marketing and distribution of amniotic fluid eye drops*

To Whom It May Concern:

The Dry Eye Foundation is a 501(c)(3) nonprofit organization serving the ocular surface disease and ocular surface pain patient communities. Our activities include public education about eye drop safety. (1)

On September 20, 2022, Sandra Brown MD, the Foundation's medical advisor, communicated to you in writing our concerns about your unlawful distribution of biologic eye drops. (2) Detailed references were provided.

On October 5 and November 17, 2022 respectively, the Food and Drug Administration published Untitled Letters to the manufacturers of Regener-Eyes (3) and StimulEyes (4) about their unlawful marketing and sale of these biological products. Dr. Brown made further communications to Dry Eye Rescue with links to these letters. (5)

On April 10, 2023, the FDA published a Public Safety Notification (6) informing patients and health care practitioners about "significant safety concerns" associated with the marketing and distribution of amniotic fluid eye drops without the required premarket FDA review and approval, with specific reference to Regener-Eyes and StimulEyes eye drops.

**As a matter of public safety, the Dry Eye Foundation urges you to stop selling Regener-Eyes brand eye drops.**

We remind you that Regener-Eyes eye drops are preservative-free and are packaged in simple multi-dose bottles. (7) This is the same packaging safety violation highlighted by both the Centers for Disease Control and the FDA in relation to EzriCare Artificial Tears, which has been linked to multiple treatment-resistant infections resulting in three deaths, eight cases of vision loss and four enucleations (8) (9).

We urge you to contact the FDA's Center for Biologics Evaluation and Research at 240-402-7912 for any questions you may have regarding the 4/10/2023 Public Safety Notification on Amniotic Fluid Eye Drops.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Rebecca Petris', with a stylized flourish at the end.

Rebecca Petris  
President

NOTES:

- (1) [eyedropsafety.org](http://eyedropsafety.org)
- (2) Letters from DEF to ABB Optical and Dry Eye Rescue (9/20/22)
- (3) [Untitled Letter to Regener-Eyes LLC](#) (FDA, 10/5/2022)
- (4) [Untitled Letter to M2 Biologics LLC](#) (FDA, 11/17/2022)
- (5) Emails from DEF to Dry Eye Rescue (10/28/22 and 11/29/22)
- (6) [Public Safety Notification on Amniotic Fluid Eye Drops](#) (FDA, 4/10/2023)
- (7) [Regener-Eyes bottle](#) (DEF YouTube channel)
- (8) [Outbreak of Extensively Drug-resistant Pseudomonas aeruginosa Associated with Artificial Tears](#) (CDC, 3/21/2023 update)
- (9) [FDA warns consumers not to purchase or use EzriCare Artificial Tears due to potential contamination](#) (FDA, 2/2/2023)