

March 9, 2023

Jordan Morgan  
President  
M2Biologics LLC  
510 Commerce Park Drive SE  
Marietta, GA 30060

**OPEN LETTER TO M2BIOLOGICS LLC**

***What is in StimulEyes?  
Is the bottle safe?***

Dear Mr. Morgan:

The Dry Eye Foundation is a 501(c)(3) nonprofit organization (1) serving the ocular surface disease and ocular surface pain patient communities. We provide platforms for mutual education, support and encouragement across the international community of patients, and we advocate for patient-centered research into effective treatments for the multifactorial conditions collectively referred to as dry eye disease.

As part of our education mission, we are actively engaged in raising awareness about safety trends of concern in the over-the-counter eye drop space (2) (3).

**In January 2022**, we first began investigating safety concerns related to biologic eye drops on behalf of our community. The primary concern was the bottle types, which offer no protection against bacterial contamination, in apparent violation of the Code of Federal Regulations Title 21 Section 200.50(b) (4).

**In April 2022**, Dry Eye Foundation began communicating with the Food and Drug Administration's Center for Biologics Evaluation and Research about biologic eye drops. Our stated concerns included but were not limited to: (a) absence of a backwash prevention device in the bottle, which we believed to be unprecedented for commercialized preservative-free multi-dose OTC substances intended for use on the ocular surface; (b) absence of a stated indication for use; and (c) absence of evidence that clinical trials had been completed to establish the safety of the products. CBER confirmed to us that products which contain or are derived from amniotic fluid require premarket approval in order to be marketed for any medical application (5).

Dry Eye Foundation  
Dry Eye Zone

Dry Eye Foundation

Dry Eye Foundation

PO Box 1891  
Poulsbo WA 98370  
800-484-0244

**In April 2022**, I received a communication from M2Biologics' Sales Director stating that StimulEyes (a) is "only available by prescription from a licensed provider", and "is a biologic, not a drug".(6) M2Biologics' website stated that "StimulEyes relies on its unique matrix, which is derived safely and ethically from human amniotic fluid. Its biological makeup is hyaluronic acid, cytokines, and growth factors" and that "clinical trials are not required" (7).

**In May 2022**, Dry Eye Foundation launched a public education campaign about biologic eye drop safety. This campaign began with presentations by our medical advisor (8), the first of which (9) addresses concerns associated with potential bacterial contamination of preservative-free eye drops in multi-dose bottles.

**In July 2022**, Dry Eye Foundation publicly identified StimulEyes as a biologic eye drop of concern (10). In ensuing months our medical advisor produced several educational presentations related to StimulEyes.

**On September 20, 2022**, the Food and Drug Administration made public a Warning Letter to Biolab Sciences, the former contract manufacturer of StimulEyes (11).

**By September 28, 2022**, M2Biologics had removed all content from its public-facing website except the home page, which stated: "A Regenerative Medicine Solution For Dry Eyes / StimulEyes relieves the symptoms of dry eye by reducing inflammation and providing lubrication" (12).

**On November 5, 2022**, attorneys for Neobiosis, the current contract manufacturer of StimulEyes, sent a Demand to Cease and Desist letter to Dry Eye Foundation and its medical advisor.

**On November 17, 2022**, the Food and Drug Administration sent an Untitled Letter to M2Biologics (13).

**By December 11, 2022**, M2Biologics had launched a new site, with a portal for consumers and eye care providers to purchase StimulEyes. The new site contains no language referencing biomaterials. (14).

**On February 1, 2023**, the Center for Disease Control and Prevention issued an emergency HAN alert (15) about Ezricare Artificial Tears, which has been linked to a multi-state outbreak of multi-drug resistant *Pseudomonas aeruginosa* infections, with outcomes including loss of vision and one death. Ezricare Artificial Tears and Delsam Pharma Artificial Tears have since been recalled (16). ***Both CDC and FDA drew attention to the fact that these products, though preservative-free, were packaged in [simple] multi-dose bottles (15) (17).***

**On February 21 2023**, I purchased StimulEyes online (\$229) from M2Biologics' website, which says it "contains no preservatives" and describes it as having "natural, scientifically studied ingredients including hyaluronic acid" (Image 1). My order was later refunded. There is a notice on the site stating that online ordering is currently unavailable (Image 2).

**On February 25, 2023**, I purchased StimulEyes from dryeyerescue.com.

**On Monday, March 6**, I received my shipment. The bottle is of a conventional type with no MDPF dropper to prevent contamination of the contents after opening (18). The label calls it an "allograft" (Image 3). The package insert mentions "bio-active components" and "donor biomaterial" (Image 4). None of this information was on either M2Biologics' website (Images 1, 2) or DryEyeRescue's website (Image 5).

## **We therefore ask in this Open Letter:**

### **1. What is in StimulEyes? Is it biologic? Is it preservative-free, as advertised?**

StimulEyes has no National Drug Code. It is not listed on DailyMed.

There is no ingredient list on the StimulEyes bottle, box or package insert.

### **2. If StimulEyes is preservative-free, how is bacterial contamination prevented during use, given that it is packaged in a simple multi-dose bottle?**

The dropper visibly sucks liquid back into the bottle after dispensing a drop. (18)

The package insert states "Product can be stored at ambient temperature... up to the 'Use by' date".(Image 5)

What evidence do you have that this packaging protects the contents from bacterial contamination in satisfaction of 21 CFR 200.50(b)?

The Dry Eye Foundation eagerly anticipates a definitive resolution to the questions of what is in StimulEyes and whether it is subject to bacterial contamination after opening.

Sincerely,

A handwritten signature in black ink, appearing to read "Rebecca Petris". The signature is fluid and cursive, with a large initial "R" and "P".

Rebecca Petris  
President

## **NOTES**

1. <http://www.dryeyefoundation.org>
2. <http://www.biologiceyedrops.org>
3. <http://www eyedropsafety.org>
4. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-200/subpart-C/section-200.50>
5. Email communication, April 6, 2022
6. Email communication, April 27, 2022
7. <https://web.archive.org/web/20220704173939/https://www.m2biologics.com/stimuleyes/faq/>
8. Sandra Brown MD, Board of Directors, Dry Eye Foundation
9. <https://www.biologiceyedrops.org/non-preserved-eye-drop-safety>
10. <https://www.biologiceyedrops.org/watch/fda-approval-for-biologic-eye-drops>
11. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/biolab-sciences-inc-621465-08232022>
12. <https://web.archive.org/web/20220928053241/https://www.m2biologics.com/>
13. <https://www.fda.gov/media/163465/download>
14. <https://web.archive.org/web/20221211152211/https://www.m2biologics.com/>
15. <https://emergency.cdc.gov/han/2023/han00485.asp?>
16. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/global-pharma-healthcare-issues-voluntary-nationwide-recall-artificial-tears-lubricant-eye-drops-due>
17. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination>
18. <https://youtu.be/wuszL7ZPQCo>

## **COPIES TO:**

### **Food and Drug Administration**

#### Center for Biologics Evaluation and Research

Melissa Mendoza, JD - Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality

Robert Sausville, Director, Division of Case Management

Maria Anderson, Supervisory Consumer Safety Officer, Biological Drug and Device Compliance Branch

Monique Lester, Consumer Safety Officer, Biological Drug and Device Compliance Branch

Jonathan Swoboda, Consumer Safety Officer, Biological Drug and Device Compliance Branch

#### Center for Drug Evaluation and Research

Carolyn Becker, JD, Office of Unapproved Drugs and Labeling Compliance

**Image 1**

This screenshot represents the entirety of the "About StimulEyes" section of <https://www.m2biologics.com/> as of 3/9/23.

Learn More

## Natural Ophthalmic Solution

StimulEyes eye drops have natural, scientifically studied ingredients including hyaluronic acid. The unique product matrix may provide soothing and enhanced moisture the eye needs.

StimulEyes is now available OTC and comes highly recommended by eye care providers.

### Professional Strength

Same formulation as used by eye care professionals.

### All-Natural Formula

StimulEyes contains no preservatives or drugs - only all natural ingredients.

### Sterilized For Safety

StimulEyes is processed using proprietary techniques in registered clean rooms operated under CGMP.

“

Overall, my experience with StimulEyes has been great! My eyes feel great. I can wear contact lenses for a full day with no discomfort. I can open my eyes without dryness first thing in the morning.

Dr. Andrew Lee  
Ophthalmologist

“

After trying StimulEyes, my eyes felt relief within two months. I wake up in the morning with refreshed eyes that no longer cause me blurry vision and pain. Because of my experience with StimulEyes, I will recommend this therapy for my patients.

Dr. Jennifer Lee  
Ophthalmologist

“

After using the StimulEyes product for just 2 weeks, I found a substantial improvement with my dry eyes. I am extremely pleased with the results of using StimulEyes. Thank you StimulEyes for creating a wonderful product and making my eyes feel terrific!

Dr. Andrew Lee  
Ophthalmologist

“

I have been using [StimulEyes] for two months now with phenomenal relief. It has been decades since my eyes have felt normal. The best thing is I no longer even think about or feel the uncomfortable feeling of dry eyes.

Dr. Jennifer Lee  
Ophthalmologist

\* The above are actual testimonials from StimulEyes users. M2 Biologics makes no claim or guarantee that others will have similar results.

**Image 2**

<https://www.m2biologics.com/> as of 3/9/2023

**A Natural Ophthalmic Solution to Relieve Dryness of the Eye**

A prescription-free, natural eye solution to relieve dryness, irritation, and redness. It is safe for contact lens wearers and pregnancy.

**PLACE AN ORDER**

Online Ordering of StimulEye6s is Currently Unavailable.  
We apologize for any inconvenience.

**StimulEye**  
Regenerative Eye Solution  
1 MONTH SUPPLY

**StimulEye6s**  
Regenerative Eye Solution  
0.5 ml

Image 3

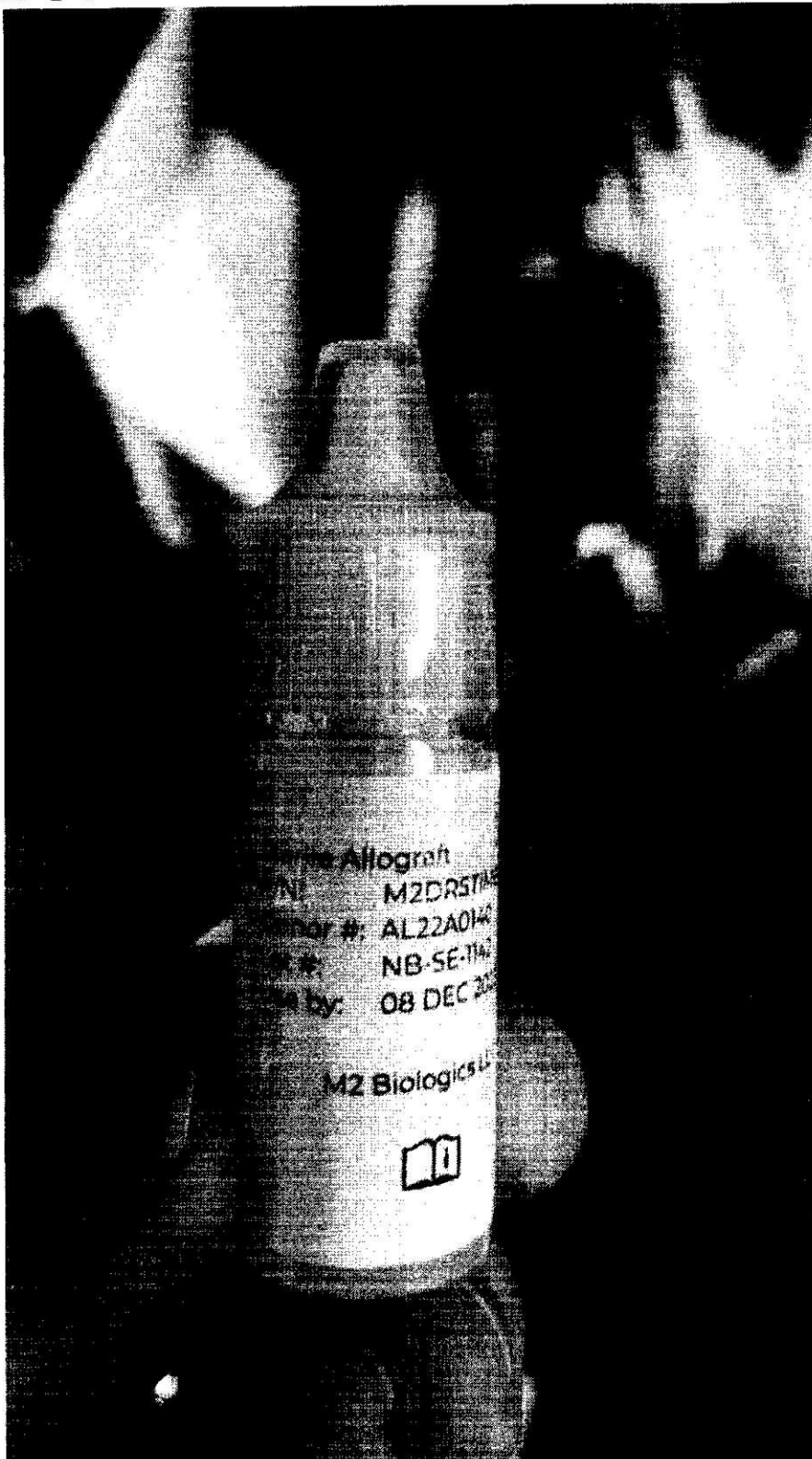
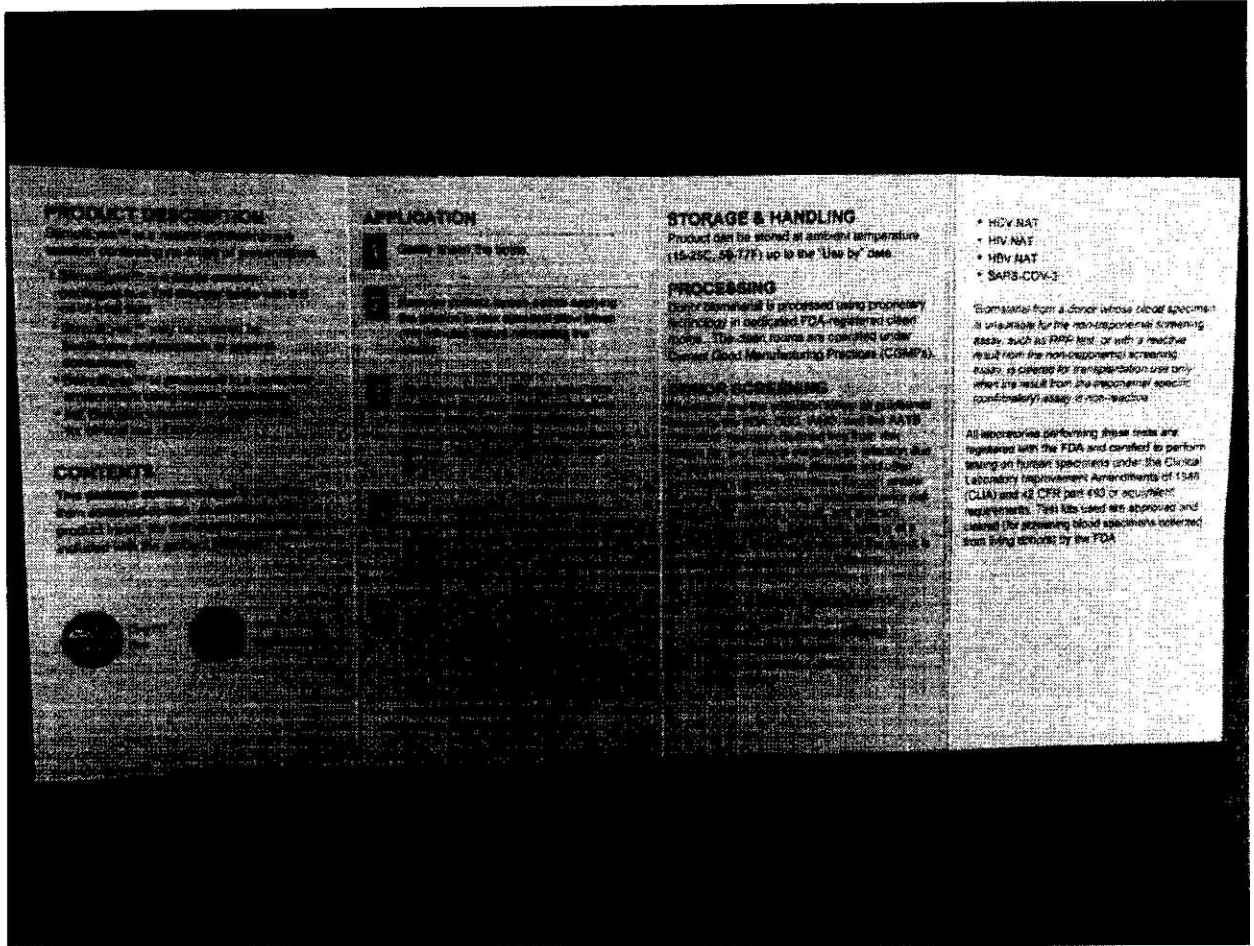



Image 4








**Image 5**

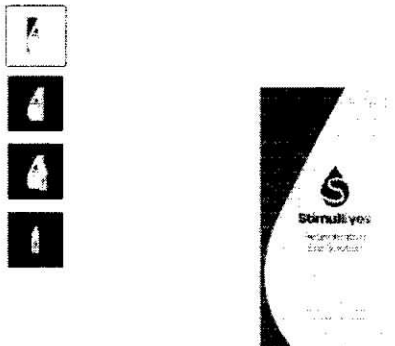
<https://driveverescue.com/products/stimuleyes-biologic-eye-drops-5-5ml-bottle-1-2-month-supply?variant=42966067085551> as of 3/9/2023.



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Roll over image to zoom in

### StimulEyes Ophthalmic solution Eye Drop PRO (5.5mL Bottle) 6-8 Week Supply


M2 BIOLOGICS SKU: DER162  
**Price: \$229.00**

Quantity: 1

Purchase Options



One-time Purchase



Subscribe and Save  
(Save 50%)

#### Description

Professional strength StimulEyes™ is a natural ophthalmic solution that has provided soothing lubrication to many who experience dryness of the eyes.

StimulEyes contains no steroids or preservatives and is applied via an easy-to-use eye dropper bottle. The product is shelf stable at ambient room temperature for two years following production. Aseptic techniques are used to process StimulEyes in a controlled environment. Product sterility is verified by an independent, third-party laboratory. No adverse reactions to this product have been reported.

Apply one drop of StimulEyes in each eye per day. If your health/eye care professional has recommended StimulEyes, then follow your provider's directions.

**SAVE UP TO 10% WITH QUANTITY DISCOUNTS**  
 Applies to any combination of products [Learn More](#)

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