

May 5, 2023

OPEN LETTER TO THE OPHTHALMIC AND OPTOMETRIC PRESS

Illegal Marketing of Unapproved Amniotic Fluid Eye Drops

Dry Eye Drugs in a Post-Truth Medical Era

Dear Editors-in-Chief and Editorial Boards:

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, in particular unapproved biologic eye drops. (1) (2)

On April 10, 2023 the FDA posted a Public Safety Notification on amniotic fluid eye drops. (3) This notification read, in part:

“There are currently no FDA-approved amniotic fluid eye drops to treat, mitigate or cure eye diseases or conditions.... In addition, as these products are not FDA-approved, the agency does not have information about their manufacture, and there are no assurances that the products are safe and effective for any disease or condition.”

Two amniotic fluid eye drops have been extensively marketed through eye care trade publications: Regener-Eyes Pro and Regener-Eyes Lite. Both are manufactured by Regenerative Processing Plant LLC and distributed by Regener-Eyes LLC.

Eye care journals such as those you publish contain materials which state the following unapproved indications for these products:

- Blepharitis
- Corneal wounds
- Corneal abrasions
- Dry eye disease (mild, moderate, severe)
- Exposure keratitis
- Filamentary keratitis
- Keratitis
- Limbal Stem Cell Deficiency
- Meibomian gland disease
- Neurotrophic pain (sic)
- Ocular surface issues resulting from surgery
- Post-surgical “issues”
- Punctate epithelial keratitis
- Recurrent corneal erosions
- Sjögrens syndrome
- Stevens-Johnson syndrome
- Post EBK re-epithelialization

Regener-Eyes LLC repeatedly uses full page advertisements to promote their products. Since 2021*, at least 42 full page ads for Regener-Eyes have appeared in at least seven different trade publications. (Attachment A) Two such advertisements were published the same month that the FDA Public Safety Notification was posted.

Regener-Eyes LLC also uses the influence of Key Opinion Leaders to market their products.

- At least 34 Key Opinion Leaders (ophthalmologists and optometrists) authored or were interviewed for articles which mention, discuss or feature Regener-Eyes eye drops. (Attachment B)
- At least 36 such articles have appeared in 12 different journals, of which 26 have been published in the past 24 months. (Attachment B)
- The KOLs include ophthalmologists and optometrists who serve on Regener-Eyes LLC's Clinical Advisory Board. (Attachment C) In a majority of articles there is no clear disclosure of this potential source of bias.
- A White Paper published as a trade journal supplement, and co-authored by a (then) Clinical Advisory Board member and the owner of Regenerative Processing Plant LLC, (Attachment D) was, until recently, a central feature of the company's advertising campaign.

Regener-Eyes LLC has never undergone a single clinical trial and cannot advertise in peer-reviewed clinical journals. Instead, its direct-to-provider marketing efforts found a natural home in the eye care industry trade magazines. Your publications unwittingly provided a veneer of legitimacy and credibility to amniotic fluid eye drops, since full-page advertisements and favorable articles by Key Opinion Leaders are typical marketing channels for FDA approved prescription drugs, and FDA compliant OTC drugs.

Damage to patient-physician relationship

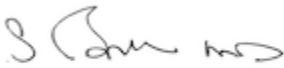
Even prior to the FDA Notification, the Dry Eye Foundation received patient phone calls and emails regarding amniotic fluid eye drops. This was often prompted by the eye drops' high cost and the aggressive telephone marketing tactics of Regener-Eyes LLC, as well as the self-evidently amateurish appearance of the bottle and label. A frequent refrain was that the drops had been recommended by their optometrists or ophthalmologists. Upon learning of the unproven and unapproved status of these products, many patients expressed dismay and distrust of their eye doctor's quality of care and knowledge, as well as concerns about financial conflict of interest.

Your eye care industry publications have therefore, regrettably, harmed the patient-physician relationship by repeatedly promoting Regener-Eyes eye drops to ophthalmologists and optometrists.

**Digital versions are not available earlier than 2021 for several of these publications.*

The Dry Eye Foundation urges the Editorial Boards and the publishers of the eye care press to develop policies which prevent the marketing of unapproved or non-compliant drugs in their journals. This would include both paid advertising, and the publication of educational articles that favorably mention these products, either by name or by drug class.

Sincerely,



Sandra Brown MD
Board Member, Medical
Advisor



Rebecca Petris
Executive Director



Aidan Moore
Deputy Executive Director

Recipients

<u>Organization</u>	<u>Name</u>	<u>Title</u>
American Society of Cataract and Refractive Surgery	Elizabeth Yeu, MD	President
EyeWorld	Sumit Garg, MD Julie Schallhorn, MD	Chief Medical Editor Cornea Editor
Modern Optometry	Selina McGee, OD Justin Schweitzer, OD Walter Whitley, OD, MBA	Chief Medical Editors
Ophthalmology Management	Larry E. Patterson, MD	Chief Medical Editor
Ophthalmology Times	David Hutton	Executive Editor
Optometric Management	Jim Thomas April Jasper, OD, FAAO	Editorial Director Chief Optometric Editor
Optometry Times	Gretchyn M. Bailey, NCLC, FAAO	Editor in Chief
Review of Optometric Business	Margery Weinstein	Editor-in-Chief
Review of Optometry; Review of Cornea & Contact Lens	Jack Persico	Editor-in-Chief
Review of Optometry	Paul M. Karpecki, OD	Chief Clinical Editor
Review of Ophthalmology	Walter Bethke Mark H. Bleacher, MD Thomas John, MD	Editor in Chief Chief Medical Editor Editor, Cornea/Anterior Segment

Notes

- (1) Eyedropsafety.org
- (2) Biologiceyedrops.org
- (3) FDA 4/10/23 [Public Safety Notification on Amniotic Fluid Eyedrops](#)

Attachments

- A: Regener-Eyes advertisements in trade journals
- B: Trade journal articles mentioning, discussing or featuring Regener-Eyes
- C: Regener-Eyes Clinical Advisory Board
- D: EyeWorld White Paper on Regener-eyes

Additional information about Regener-Eyes

- i. Packaging and labeling
- ii. Sales and distribution
- iii. Retail prices
- iv. Regulatory status claims

Attachment A - Advertisements

Full-page advertisements for Regener-Eyes appear in the following publications.
 (Note: Digital versions are not available earlier than 2021 for several of these publications.)

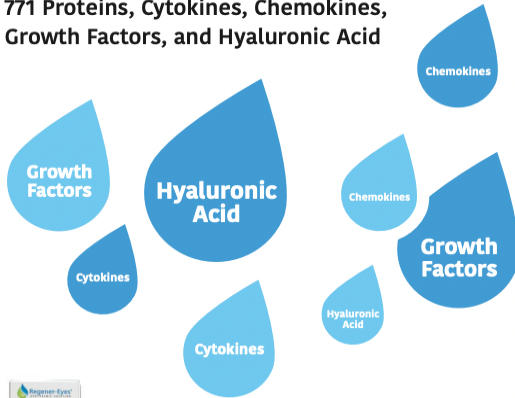
Publication	2021	2022	2023
Contact Lens Spectrum	May, July		
Ophthalmology Management	April, October, November, December	January, February, April, May, June, August, September, October	April
Ophthalmology Times	February, September		
Optometric Management	July, August, September	February, March, April, May, July, August, September, October	
Review of Ophthalmology	September, November, December	April, June, September, October	
Review of Optometry	March, September, December	February, April, June, September	
Vision Monday	April		

Examples of Regener-Eyes ads



**It's raining proteins
in every drop.**

**771 Proteins, Cytokines, Chemokines,
Growth Factors, and Hyaluronic Acid**



HEAL, REPAIR, AND REGENERATE.

mydryeyes.org | 877-206-0706

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regenereyes.com | 877-206-0706

© 2021 Regener-Eyes®, All rights reserved



Five Alarm Fire?



Extinguish it with the only biologic drop.



regenereyes.com | 877-206-0706

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THE **POWER** OF SCIENCE,
IN THE **EASE** OF AN EYE DROP™

Regener-Eyes' patented technology helps the tear film layer by increasing lubrication and hydration to the eye surface helping To Relieve Dryness of the Eye.



Attachment B - Trade journal articles

Trade journal articles which mention, discuss or feature Regener-Eyes:

- Kristine Brennan; interviewee: Darren Gregory MD (11/2016) [Thicker than Water: Autologous Serum](#), Review of Ophthalmology
- Whitney Hauser, OD (9/2018) [Clinical: Dry Eye / Mail-Order Options](#), Optometric Management
- Elizabeth Yeu, MD (12/2018) [Amniotic Derived Therapies Prove Effective in Treating Ocular Surface Disease](#), Ophthalmology Management
- Alison Bozung OD & Paul Hammong OD (8/2019) [When Corneal Wounds Won't Heal](#), Review of Optometry
- Peter Hersh, MD, James Loden MD, Luke Rebenitsch MD (4/2020) [Therapeutic Refractive Corneal Surgery](#), Eyeworld
- Michelle Dalton; interviewee: Elizabeth Yeu MD (4/2020) [Dry Eye Disease Treatment Options](#), Ophthalmology Management
- Jill Gallagher; ref. Randall Thomas OD and Ron Melton OD (10/2020) [The State of Eye Care Today](#), Review of Optometry
- Arthur Epstein OD (1/2021) [Off the Cuff: Some Secret Sauce](#), Review of Optometry
- Joe Darrah; interviewee: Cynthia Matossian MD (3/2021) [Rx Perspective: A Natural Treatment for Dry Eye](#), Ophthalmology Management
- Steven Sorkin OD (4/2021) [Corneal Dystrophies 101](#), Modern Optometry
- n/a (4/2021) [Industry Insider: Regener-Eyes Bob Colucci](#), Ophthalmology Management
- Paul Karpecki OD (4/2021) [New Options, Front to Back](#), Review of Optometry
- Ahmad Fahmy OD (5/2021) [A New Tool in the Dry Eye Armamentarium](#), Optometric Management
- Paul Karpecki OD (5/2021) [How Getting Dry Eye Right Changes Patient Lives & Easily Adds \\$100,000+ Annually](#), Review of Optometric Business
- Darrell White MD (5/2021) [Treating Dry Eye 401: A Master Class in Treating Complex Cases](#), Ocular Surgery News (5/2021) [O.D. Notebook: Maintain Patient Communication](#), Optometric Management
- Arthur Epstein OD (6/2021) [The Essentials: A Master Class in Dry Eye](#), Contact Lens Spectrum
- Kambiz Silani OD (7/2021) [Focus: Drop-in Moisture](#), Optometric Management
- Leanne Spiegle (9/2021) [Approaches and Methods for Treating Dry Eye: 2021](#), Review of Ophthalmology
- Steven Sobel OD (11/2021) [Ophthalmic Biologics](#), Modern Optometry
- Paul Karpecki OD (11/2021) [Owning OSD: New Treatments can Help Us Keep Up With This Perennial Problem](#), Review of Optometry
- Alice Epitropoulos MD (1/2022) [Treating DED in Contact Lens Patients](#), Ophthalmology Management

- Mark Tosh; interviewee Kimberly Riordan OD (2/2022) [Increasing Incidence of Dry Eye Disease Presents Opportunity for ODs](#), Vision Monday
- Frederick Ditmars BS, Kimberly Brondeel BS, W. Samuel Fagg MSC PhD, Pamela Theriot OD (3/2022) [A Double-Header: Dry Eye and Filamentary Keratitis](#), Modern Optometry
- Rachel Dandar MD, John Sheppard MD (5/2022) [Four Novel Approaches to DED Treatment](#), Ophthalmology Management
- Jerry Robben OD, Patti Barkey COE (5/2022) [How We Built Dry Eye Services That Spurred 20%+ Growth in Annual Revenue](#), Review of Optometric Business
- C. Randall Harrell MD (5/2022) [Bringing Biologics to Eye Health](#), Ophthalmology Times
- Maria Sampalis OD (5/2022) [The Technology Powering My New Dry Eye Center](#), Review of Optometric Business
- Mahnia Madan OD, Mark Eltis OD (6/2022) [From Basics to Biologics: Selecting Drops for Every Dry Eye Patient](#), Review of Cornea & Contact Lens
- Elise Kramer OD (6/2022) [Therapy Options Based on DED Severity](#), Optometry Times
- Christopher Kuc OD (7/2022) [Five Rules of Thumb for Managing the Ocular Surface](#), Modern Optometry
- Emilie Seitz OD (7/2022) [Sjögren Syndrome: Ocular Manifestations of an Underlying Systemic Disease](#), Modern Optometry
- Arthur Epstein OD (8/2022) [A Master Class in Dry Eye - Breakthroughs in Understanding and Managing Dry Eye](#), Contact Lens Spectrum
- Mitchell Jackson MD (8/2022) [Spotlight on Dry Eye: Create a Process, Offer Packages](#), Ophthalmology Times
- Carly Rose OD (11/2022) [DED: Developing a 360 Diagnosis and Treatment Plan](#), Optometry Times
- Pam Theriot OD, Lisa Hornick OD (3/2023) [Dry Eye Drugs: What's New and What's Next](#), Review of Optometry
- Catlin Nalley; interviewee James Thimons OD (3/2023) [Restrictive Drug Formularies: How to Beat the Odds](#), Review of Optometry
- Ethan Lindgren BS, Neel Pasricha MD (4/2023) [Medical Management of Dry Eye Disease](#), Ophthalmology Management

Attachment C - Clinical Advisory Board

Source: regenerereyes.com/clinical-advisory-board/ as of May 5, 2023



HOME ABOUT US ▾ OUR PRODUCTS FOR EYE CARE PROFESSIONALS ▾ FOR PATIENTS ▾ CONTACT

Clinical Advisory Board

Ophthalmologists



Eric Donnenfeld, MD



Bennett Romanoff, MD



Sandra Cremers, MD

Optometrists



Paul M. Karpecki, OD, FAAO



Arthur Epstein, OD, FAAO



Walt Whitley, OD, FAAO



Ahmad M. Fahmy, O.D., FAAO,
Dipl., ABO



Walter Choate, OD, FAAO



James Thimons, OD, FAAO

Attachment D: White Paper

Marguerite McDonald MD, Carl Randall Harrell MD (7/2021) [Therapeutic Potential of Regener-Eyes Ophthalmic Solution in the Treatment of Dry Eye Disease](#), Eyeworld Supplement

Excerpt:

“Regener-Eyes is an engineered biological product derived from human placental-based biomaterials, manufactured under current Good Manufacturing Practices (cGMP), regulated and reviewed by the Food and Drug Administration (FDA). Regener-Eyes incorporates Regenerative Processing Plant’s (RPP) proprietary patented sterilization process to provide for a safe, sterile product for clinical use.”

Conclusion:

“Regener-Eyes® drops are a topical therapy for DED; they are an engineered biological product. The drops contain a large number of anti-inflammatory and trophic factors that attenuate the detrimental immune response in the eye and protect the epithelial cells of the ocular surface from injury and inflammation.^{1,9,12–13,15} Topical administration of Regener-Eyes® may suppress ongoing ocular inflammation, may improve meibomian gland function, and may enhance the restoration of the ocular surface barrier in DED patients, without causing treatment-related adverse events.^{1,13} Due to its potent immunosuppressive and regenerative properties, Regener-Eyes® should be considered as a powerful new therapeutic option in the management of DED.”

ASCP EYEWORLD WHITE PAPER

Therapeutic potential of Regener-Eyes® Ophthalmic Solution in the treatment of dry eye disease

by Marguerite McDonald, MD, clinical professor of ophthalmology, NYU Langone Medical Center, New York, New York; clinical professor of ophthalmology, Tulane University Health Sciences Center, New Orleans, Louisiana; cornea/cataract/refractive surgeon and director of the dry eye center of excellence, OCLI Vision, Oceanside, New York; and Carl Randall Harrell, MD, Regenerative Processing Plant, Palm Harbor, Florida

Abstract

Dry eye disease (DED) is a common and multifactorial disease of the ocular surface characterized by a deficiency in quality and/or quantity of the tear fluid. A detrimental immune response has an important role in the development and progression of DED. Dr. Harrell recently developed Regener-Eyes® (generic name “derived-Multiple Allogeneic Proteins Paracrine Signaling [d-MAPPS]”), an ophthalmic solution that contains a large number of immunoregulatory factors that are capable of penetrating the ocular surface and to efficiently attenuate the detrimental immune response in the eye, promoting repair and regeneration of injured tissue. Regener-Eyes® efficiently alleviated DED-related symptoms (dryness, grittiness, scratchiness, soreness, irritation, burning, watering, foreign body sensation, eye fatigue) and improved functional visual acuity in 131 DED patients, without causing any side effects.² Herewith, we described in detail the molecular mechanisms and signaling pathways that are responsible for the immunomodulatory effects of Regener-Eyes®, thereby exploring the therapeutic potential of Regener-Eyes® in the treatment of DED.

Introduction

Dry eye disease (DED) is a common and multifactorial inflammatory disease of the ocular surface characterized by a deficiency in quality and/or quantity of the tear fluid.¹ The multifactorial nature of DED involves several interrelated underlying pathologies, including the loss of homeostasis, instability and hyperosmolality of the tears, and chronic eye inflammation that leads to the neurosensory dysfunction and visual disturbance. Accordingly, DED is usually manifested by dryness, grittiness, scratchiness, soreness, irritation, burning, watering, foreign body sensation, eye fatigue, and reduced functional visual acuity. Significantly impaired performance of vision dependent daily activities (reading, writing, driving) often diminishes the quality of life of DED patients.²

A detrimental immune response has played a crucially important role in the development and progression of DED. Accordingly, DED-related symptoms are often observed in patients who suffer from chronic inflammatory and systemic autoimmune diseases (Sjögren’s syndrome, rheumatoid arthritis, systemic lupus erythematosus).^{3,7} Considering the important role of inflammation in DED development, the main treatment strategy has shifted from hydration and lubrication of the dry ocular surface to the immunoregulation-based therapeutic approach, which is designed to break the vicious cycle of chronic inflammation in the

eye.²⁻⁶ The administration of immunosuppressive eye drops has the potential to attenuate the ongoing inflammation, resulting in the alleviation, as the well-developed protective mechanisms of the ocular surface ensure their rapid clearance from the pre-corneal tear film, thus limiting ocular penetration of the drug.⁸ Therefore, there is a large unmet need for the development and clinical use of eye drops containing immunomodulatory factors that are able to bypass the ocular surface barrier and reach the target cells of the ocular surface and lacrimal system.⁸

In line with these findings, Dr. Harrell recently developed Regener-Eyes® (generic name “derived-Multiple Allogeneic Proteins Paracrine Signaling [d-MAPPS]”), an ophthalmic solution that contains a large number of immunoregulatory factors that are capable of penetrating the ocular surface to efficiently attenuate the eye’s detrimental immune response, which may help to promote the repair and regeneration of damaged corneal tissue.⁹ Herein, we described in detail the molecular mechanisms and signaling pathways that are responsible for the immunomodulatory effects of Regener-Eyes®, exploring the therapeutic potential of Regener-Eyes® in the treatment of DED.

Molecular mechanisms responsible for beneficial effects of Regener-Eyes® in DED treatment

Although Regener-Eyes® is acellular, it contains proteins, cytokines in addition to the water, glucose, lactates and electrolytes, and placental-derived biomaterials, which produce a large

number of bioactive factors (lipids, proteins, enzymes, cytokines, chemokines, immunoregulatory proteins, trophic and growth factors), as well as microRNAs (miRNAs), which, due to their trophic and antimicrobial properties, support normal fetal growth and offer protection against pathogens and toxins.¹⁰ Additionally, these placental biomaterials contain AF-MSC-sourced exosomes (AF-MSC-Exos), nano-sized extracellular vesicles that are enriched with AF-MSC-derived immunosuppressive molecules and growth factors.¹⁰⁻¹¹ Due to their nano-sized dimensions and lipid envelope, AF-MSC-Exos avoid biological barriers, and easily penetrate through the lipid-containing cell membranes of the ocular surface through direct fusion with the plasma membrane, thereby delivering their content to the cytosol of target cells.¹⁰⁻¹²

Regener-Eyes® is an engineered biological product derived from human placental-based biomaterials, manufactured under current Good Manufacturing Practices (cGMP), regulated and reviewed by the Food and Drug Administration (FDA).⁹ Regener-Eyes® incorporates Regenerative Processing Plant’s (RPP) proprietary patented sterilization process to provide for a safe, sterile product for clinical use.⁹ Regener-Eyes® is enriched with AF-MSC-Exos containing AF-MSC-derived immunoregulatory, angio-modulatory and trophic factors capable of bypassing biological barriers to efficiently attenuate ongoing inflammation, promoting enhanced tissue repair and regeneration.⁹ Specifically, Regener-Eyes® contains interleukin 1 receptor antagonist (IL-1RA), soluble receptors of tumor necrosis factor alpha

Additional Information

i. Regener-Eyes packaging and labeling

Package of Regener-Eyes purchased by Dry Eye Foundation in April 2022



GENERAL DESCRIPTION
 RegenerEyes Lite™ Ophthalmic Solution is a versatile and convenient biologic in eye and form.
 RegenerEyes Lite™ should be discussed with your vision professional prior to use.
 RegenerEyes Lite™ is a sterile solution packaged in a 3 ml bottle.
 RegenerEyes Lite™ is distributed exclusively by RegenerEyes, Inc. to vision health care professionals (i.e., Ophthalmologists, Optometrists, etc.) through health care providers by means of RegenerEyes Processing Plant, LLC's (RPP) indirect protected processes.
 RPP assumes no responsibility for the clinical use of this product.

STORAGE INSTRUCTIONS AND PRECAUTIONS
 It is recommended that RegenerEyes Lite™ be stored in a cool dry place once opened.

INSTRUCTIONS FOR USE
 1. Remove bottle from package.
 2. Shake the dropper to mix the ingredients.
 3. To open, hold the bottom of the vial securely and twist the top. Remove top.
 4. Wash your hands, tilt head back, lift upper eye lid with finger and position the dropper as close to the eye as possible being careful not to touch the vial tip to eye tissues.
 5. Apply 1 drop of RegenerEyes Lite™ to each eye, or as health care professional recommends.
 6. Return remaining product to cool dry place. Wash hands.
 7. Reapply as directed.

DONOR SCREENING AND TESTING
 Prior to processing, the donor is screened for conditions or disease processes that would contraindicate the donation of tissue. All policies and procedures for donor screening, serologic and microbiologic testing meet current regulations established by the FDA and other state and local governing bodies. Contraindications for tissue donation include: presence of infectious disease, neurological degenerative disease, disease of unknown etiology, and exposure to toxic substances. The donor is also screened for HIV, hepatitis, and other relevant communicable disease agents in accordance with current United States Public Health Service recommendations and FDA Federal Regulations and Guidance Documents.

Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments (CLIA) and 42 CFR Part 493, or that has equivalent requirements as determined by the Centers for Medicare and Medicaid Services. Names and addresses of testing laboratories, interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records are kept on file at the processing tissue bank.

Donor blood samples taken prior to or at the time of recovery were tested by laboratories certified under the CLIA and were found negative using FDA licensed tests for, at minimum:

- HBsAg: Hepatitis B Surface Antigen
- HBcAb: Hepatitis B Core Antibody
- HCVAb: Hepatitis C Antibody
- HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody
- HCV NAT: Hepatitis C Virus
- HIV NAT: Human Immunodeficiency Virus
- HBV NAT: Hepatitis B Virus
- RPR/STS or Equivalent: Syphilis
- WNV: West Nile Virus

PROCESSING AND STERILITY

Donor biomaterials are recovered using the safest recovery techniques and sterile equipment to minimize any bio burden contamination. RPP biomaterials are procured via a network of qualified and trained recovery partners, one of the most stringent screening and recovery protocols, and a highly controlled processing environment, thus countering the risks of disease transmission at every step. All biomaterials are processed sterile utilizing RPP's proprietary patent protected processes.

ADVERSE REACTION

There have been no reported adverse reactions associated with RegenerEyes™ Ophthalmic Solution. However, general risks and complications are inherent, but are well known to ophthalmologists. Solution should be reported immediately to RPP's Customer Service department at (800) 781-0218.

WARNINGS AND PRECAUTIONS

RegenerEyes™ Ophthalmic Solution must not be used under the following conditions:
 • If resurfacing has caused possible damage or contamination, or the product is past its expiration date.
 • If any of the elements, packaging, fill-in, and/or barcodes are missing, damaged, illegible, or defaced.
 • If it has not been stored according to instructions or form is not intact.
 Notify RPP immediately if any of the aforementioned conditions exist or are suspected.

TRACKING

Regulations and tracking are outlined for the final disposition. RPP provides a Tissue Tracking Record (TTR) with every box of RegenerEyes™ Ophthalmic Solution™. In order for the consignee to comply, they must complete the pre-printed TTR by recording the information requested. RPP has supplied pre-printed labels and a HIPAA compliant self-mailer for every submission. TTRs must be returned to the processor within 15 days following transplantation.
 Discard RegenerEyes™ Ophthalmic Solution is NOT exempt from TTR compliance.


Ingredients:
 Sterile Ophthalmic Solution

Sterile Water

RETURN POLICY

RPP does not accept the return of RegenerEyes™ Ophthalmic Solution products unless it is received damaged or defective. If you experience a problem with your product, notify RPP immediately for a Returned Material Authorization (RMA) number at (800) 781-0218.

SECURITY, RETRIEVAL, PROCESSING, AND DISTRIBUTION

 <p>RegenerEyes Processing Plant, LLC</p>	<p>RegenerEyes Processing Plant, LLC 84276 US HWY 198 Palm View, TX, 75668 1 800 781 0218</p>
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PACKAGE IDENTIFICATION	
STERILE	A
LOT	Processed for sterility by RegenerEyes Processing Plant's patent protected process.
SN	Lot Number
	Fluid Identifying Number (Serial Number)
	Single patient use only
	Prescription required to order
	See Package Insert Instructions for Use

Package of Regener-Eyes, purchased by Dry Eye Foundation in February 2023:
 For bottle, watch: <https://youtu.be/onMQAYlmmLc>
 (Tip: Turn up volume.)




ii. Regener-Eyes distribution and sales

Distributor ABB Optical

The screenshot displays the ABB Optical website's product page for Regener-Eyes LITE. At the top, a navigation bar includes links for ABOUT ABB, ABBY, BECOME A MEMBER, CAREERS, NEWS, RETURNS PROGRAM, ABB ANSWERS, CONTACT, NEWSLETTER SIGN UP, REGISTER, and LOGIN. Below this is a secondary menu with ABB Contact Lens, ABB Labs, ABB Business Solutions, and Resources. The main content area features a circular image of an eye with a contact lens being applied. To the right is the Regener-Eyes LITE logo and a descriptive paragraph: "With Regener-Eyes Lite®, you can maintain your patient's continuity of care by recommending a product available exclusively through YOU, their eye care professional. Regener-Eyes, a first in class, natural, sterile ophthalmic solution that is preservative-free and is available to ship directly to your patient. This non surgical, long lasting solution is offered in a convenient eye drop." Below the text are two buttons: ORDER NOW and DOSAGE/INFO. A second navigation bar is visible below the main content, identical to the first. The lower portion of the screenshot shows a testimonial section with the heading "Here's what one optometrist had to say:" and a quote from Paul M. Karpecki OD, FAAO: "Having the opportunity to prescribe Regener-Eyes has really changed the lives of many of my patients. The response has been remarkable." A portrait of Paul M. Karpecki is shown to the right. At the bottom, a call-to-action section asks "Ready to Order?" and provides instructions to login to an ABB Account or contact an ABB Account Manager.

Physician Regener-Eyes referral process/portal



HOME ABOUT US ▾ OUR PRODUCTS FOR EYE CARE PROFESSIONALS ▾ FOR PATIENTS ▾ CONTACT

About

Regener-Eyes® is an OTC Drug **To Relieve Dryness of the Eye.**
It is available in Professional and LITE Strengths.

The **Power** of Science, in the **Ease** of an Eye Drop.™

Step 1: Register

Please complete the online Eye Care Professional (ECP) registration form below.

(If you have already registered, please go straight to Step 2)

[REGISTRATION FORM](#)


Step 2: How to recommend Regener-Eyes®



To recommend Regener-Eyes® for your patients, please complete the form below. We will contact the patient(s), collect payment, and ship directly to their home.

[ONLINE RECOMMENDATION FORM](#)

If you are interested in stocking Regener-Eyes® and having a new product line for your office, please email or call us

E-commerce Regener-Eyes sales



Search... All categories ▾  Login / Signup My account  Cart

All Products Shop by Type ▾ Shop by Brand ▾ In-Office Treatments ▾ Doctor Locator Dry Eye Clinics Contact Rewards [Doctor Login](#)

Filters



Availability ▾

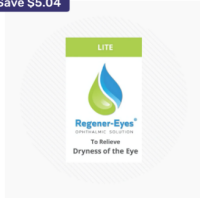


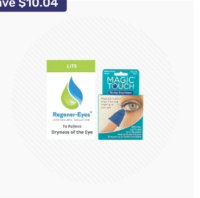

Price ▾

Product type ▾

Brand ▾

Products for "regener-eyes"

Showing 1 - 5 of 5 results Display: 24 per page ▾ Sort by: Relevance ▾ View  

<p>Save \$5.04</p>  <p>\$84.95 \$89.99</p> <p>Regener-Eyes Lite Eye Drops (3mL Bottle, 3-4 Week Supply)</p> <p>REGENER-EYES</p>	<p>Save \$45.04</p>  <p>\$199.00</p> <p>Regener-eyes PRO Eye Drops (3mL Bottle, 3-4 Week Supply)</p> <p>REGENER-EYES</p>	<p>Save \$45.04</p>  <p>\$224.95 \$269.99</p> <p>Regener-Eyes Lite 3-Pack Eye Drops (3 x 3mL Bottles, 2 Month Supply)</p> <p>REGENER-EYES</p>	<p>Save \$10.04</p>  <p>\$89.95 \$99.99</p> <p>Regener-Eyes Lite with Magic Touch Easy Applicator (3mL Bottle, 4 Week Supply)</p> <p>REGENER-EYES</p>
<p>Save \$93.04</p> 			



Search...

All categories



Login / Signup
My account



All Products Shop by Type Shop by Brand In-Office Treatments Doctor Locator Dry Eye Clinics Contact Rewards [Doctor Login](#)

Shipping Notice

Regener-Eyes products can now be shipped without being Cold, but still require Overnight or 2-Day Shipping. Shipping rates do apply for Regener Eyes Lite and Pro. This can ONLY be shipped Monday - Thursday to avoid Shipping Delays and Product Damage.

** Shipping date will depend on RX confirmation. Please make sure to email us a copy of your prescription or your date of birth and doctors contact information **

Description

About

Regener-Eyes® is an **OTC Drug that is preservative free.**

Regener-Eyes® Ophthalmic Solution, Professional Strength, and LITE are used as a lubricant to prevent further irritation or To Relieve Dryness of the Eye.

Regener-eyes PRO Eye Drops (3mL Bottle, 3-4 Week Supply)

REGENER-EYES

Price: **\$199.00**

Quantity: - 1 +

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LOCAL SPECIALISTS IN YOUR AREA

Please enable your location. We need to know where you are in order to suggest you providers nearby.

THE EYE DOCTOR SHOP

DRY EYE MACULAR DEGENERATION BLUE LIGHT GLASSES COSMETICS OUR EYE DOCTORS LEARNING CENTER

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Regener-Eyes® Ophthalmic Solution - Professional Strength

\$199.00

Purchase Options

One Time Purchase \$199.00

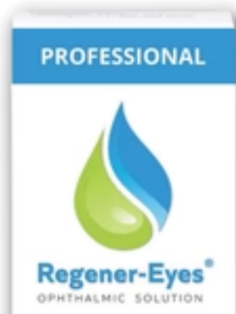
Subscribe and save \$189.05

Subscription detail

- 1 +

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Click to expand

Regener-Eyes® Professional Strength Eye Drop



Be the first to review this product

Earn 1 point for writing a review for this product

Regener-Eyes® is a Safe and Effective, preservative-free option To Relieve Dryness of the Eye. Its patented technology is trademarked and formulated under the principle to "follow the science" which is the single most important standard of the company. Regener-Eyes truly is The Power of Science, in the Ease of an Eye Drop.™ Regener-Eyes' patented technology assists the tear film layer by increasing lubrication and hydration which promotes homeostasis of the corneal surface and helps slow down the cycle of dry eyes.



\$170.00


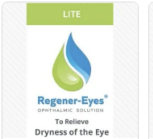


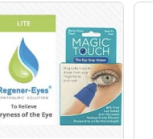

Patient Certification *

I certify that Dr. Kuriachan or another eye care provider has recommended this product for me.

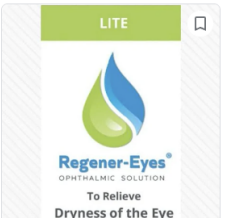
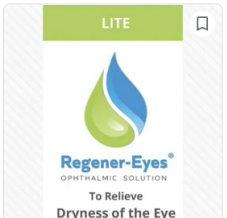
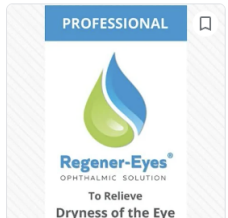
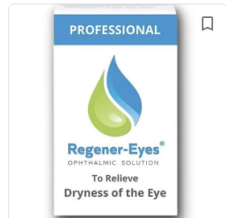
iii. Regener-Eyes retail prices

\$84.00 to \$199.00 for 3mL bottle

Sponsored · Shop regener-eyes :

 <p>Regener-eyes PRO 3-Pack Eye Drops (3 x 3mL Bottles, 2-3...) \$506.95 DryEye Rescue Free shipping</p>	 <p>Regener-Eyes Lite Eye Drops (3mL Bottle, 3-4 Week...) \$84.95 DryEye Rescue</p>	 <p>Regener-eyes PRO Eye Drops (3mL Bottle, 3-4 Week...) \$199.00 DryEye Rescue</p>	 <p>Regener-Eyes Ophthalmic Solution - Professional... \$199.00 The Eye Doctor Sh...</p>	 <p>Regener-Eyes Lite with Magic Touch Easy Applicator... \$89.95 DryEye Rescue Free shipping</p>	 <p>Regenerative ECM Eye Complex \$122.00 mdaire.com ★★★★★ (33) Free shipping</p>
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About these results

 <p>Regener-Eyes OPHTHALMIC SOLUTION To Relieve Dryness of the Eye Regener-Eyes Lite Eye Drops (3ml Bottle, 3-4 Week Supply) Contact Lens Safe \$84.95</p>	 <p>Regener-Eyes OPHTHALMIC SOLUTION To Relieve Dryness of the Eye Regener-Eyes Lite Eye Drops (3mL Bottle, 3-4 Week Supply) Contact Lens Safe \$84.00</p>	 <p>Regener-Eyes OPHTHALMIC SOLUTION To Relieve Dryness of the Eye Regener-eyes Pro Eye Drops (3ml Bottle, 3-4 Week Supply) Single-use · Liquid Drops \$199.00</p>	 <p>Regener-Eyes OPHTHALMIC SOLUTION To Relieve Dryness of the Eye Regener-Eyes Ophthalmic Solution - Professional Strength Contact Lens Safe \$199.00</p>
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iv. Regener-Eyes' regulatory status claims (examples)

Regener-Eyes Press Release 5/1/2023:

[Regener-Eyes® Announces New Peer Reviewed Scientific White Paper on Regener-Eyes an Ophthalmic Solution to Relieve Dryness of the Eye](#)

(Note: This press release was issued three weeks after the [FDA Public Safety Communication on Amniotic Fluid Eyedrops.](#))

“Regener-Eyes is... in full compliance with all FDA regulations”

NEWS PROVIDED BY
Regener-Eyes →
May 01, 2023, 08:00 ET

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TAMPA, Fla., May 1, 2023 /PRNewswire/ -- Regener-Eyes® is regulated as an OTC drug product that is registered and in full compliance with all FDA regulations. The Regener-Eyes® family is excited to announce that our Founder, CEO, and Chief Medical Officer, C. Randall Harrell, M.D., has just published a peer-reviewed scientific white paper on Regener-Eyes®, an ophthalmic solution To Relieve Dryness of the Eye.

Regener-Eyes website

“Regener-Eyes is in compliance with all Federal regulatory laws”

<https://www.regenereyes.com/our-products/> as of May 5, 2023



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Eye.

Technology

Regener-Eyes® Ophthalmic Solution helps increase lubrication and hydration of the corneal surface. This helps to

Regener-Eyes® Ophthalmic Solution has an excellent safety profile.

Regener-Eyes® is non-steroidal. Instead, it helps to protect and relieve dryness of the eye.

Each product is preservative-free.

Each batch of Regener-Eyes® is tested to ensure quality, sterility, and safety.

Regener-Eyes is in compliance with all Federal regulatory laws.

Dosage and Administration

Regener-Eyes exhibitor profile

American Academy of Optometry event page, October 2022

“Regener-Eyes is in compliance with all Federal regulatory laws”

The screenshot shows the exhibitor profile for Regener-Eyes at the American Academy of Optometry event in San Diego, October 26-29, 2022. The page features a navigation menu on the left with options like Home, My Account, and Apply for Booth Space. The main content area displays the company name, location (Tampa, FL), website, and social media links. A 'Categories' box lists 'Contact Lenses, Accessories and Solutions' and 'Other'. The profile text describes the product as a hypotonic solution for eye dryness, highlighting its safety and compliance with federal regulations.

See you in Cali!
OCTOBER 26-29, 2022
Presented by AMERICAN ACADEMY of OPTOMETRY

Centennial Celebration
ACADEMY 2022
san diego

Home
My Account
Apply for Booth Space
General Information
Live Floor Plan
Exhibitor List & Floor Plan
Booth Personnel Registration | Hotel Reservation
Exhibitor Frequently Asked Questions (FAQs)

Regener-Eyes®
Tampa, FL
United States
<https://www.regenereyes.com/>
t f in

Regener-Eyes®
OPHTHALMIC SOLUTION

Categories
Products/Services
• Contact Lenses, Accessories and Solutions
• Other

Booth: 805 Notes ☆

The POWER of Science, in the EASE of an eye drop.

Regener-Eyes® Ophthalmic Solution, contains a hypotonic solution, increasing dwell time, lubricating and hydrating the corneal surface, to relieve dryness of the eye.

Regener-Eyes® Ophthalmic Solution has an excellent safety profile.

Regener-Eyes® is not steroidal. Instead, it uses the body's own ability to protect & Relieve Dryness of the Eye.

Each batch of Regener-Eyes® is tested to ensure quality, sterility, and safety.

Regener-Eyes® is in compliance with all Federal regulatory laws.