U.S. FOOD & DRUG ADMINISTRATION

October 05, 2022

VIA UPS EXPRESS MAIL

Randall Harrel, M.D.
Chief Executive Officer and Chief Marketing Officer
Regener-Eyes, LLC
34176 US Hwy 19 N
Palm Harbor, FL 34684

Dear Dr. Harrel:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) has reviewed your firm's website available at www.regenereyes.com as well as other information available to FDA.

You market a "natural, ophthalmic solution," described as an "acellular" "biological product" that is composed of "placental-derived biomaterials" referred to as Regener-Eyes® Ophthalmic Solution, (hereinafter, "your product") to mitigate or treat Dry Eye Disease.[1]

Based on your internet statements, your product is intended to, among other things, cure, mitigate, treat, or prevent diseases or conditions in humans and therefore appears to be a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 321(g)]. Additionally, your product appears to be a biological product under section 351 of the Public Health Service Act (PHS Act) [42 U.S.C. 262(i)], because it is applicable to the prevention, treatment, or cure of a disease or condition of human beings.

In order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after a demonstration that the product is safe, pure, and potent. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug application (IND) in effect as specified by FDA

[1] Please note that human cells, tissues, or cellular or tissue-based products (HCT/Ps) are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 CFR 1271.3(d). If your product consists of amniotic fluid, please be advised that the definition of HCT/Ps excludes secreted or extracted human products. 21 CFR 1271.3(d)(3). Accordingly, secreted body fluids, such as amniotic fluid, are not considered HCT/Ps and are not regulated under section 361 of the Public Health Service Act and the regulations in 21 CFR Part 1271.

regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312]. Your product is not the subject of an approved biologics license application (BLA), nor is there an IND in effect for your product.

Manufacturers and health care professionals who have any uncertainty regarding the regulatory status of their products are encouraged to contact FDA to obtain a recommendation or decision regarding the classification of their products.

For example, you may submit a Request for Designation (RFD) to FDA's Office of Combination Products (OCP) to obtain a formal FDA decision regarding the regulatory identity or classification of your product (21 CFR Part 3). A description of that process and information on how to submit an RFD can be found at: https://www.fda.gov/combination-products/rfd-process. Additional information may be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd. You may also submit a Pre-RFD to OCP to obtain preliminary feedback on the classification of your product as well as assistance on how to prepare an RFD. Additional information may be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd.

Further information about IND requirements for biological products may be obtained through the Division of Regulatory Project Management, Office of Tissues and Advanced Therapies, at (240) 402-8190 or OTATRPMS@fda.hhs.gov.

This letter is not intended to be an all-inclusive review. You and your firm are responsible for ensuring that all your products fully comply with the FD&C Act, PHS Act, and all applicable regulations. We request a written response within 30 days of your receipt of this letter. If you do not believe there is a basis for the regulatory issues raised in this letter, include your reasoning and any supporting information for our consideration.

Your response should be sent to the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 71, Silver Spring, MD 20993. In addition, you may also email a copy of your official, written response to CBERDCMRecommendations@fda.hhs.gov. If you have any questions regarding this letter, please contact the Division of Case Management, CBER at (240) 402-9156. Please be advised that only written communications are considered official.

Sincerely,

Melissa J. Mendoza
Acting Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Cc:
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