The FDA would like to remind you not to put amniotic fluid in your eyes

Enlarge / An inflamed eye.

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For a sinister Shakespearian brew to conjure spirits, you're going to need to gather a variety of mystical herbs, like the scale of a dragon and the cool blood of a baboon (or maybe a spotted gecko). For eternal life, harvest a dead man's toe and a newt's saliva.

But if dry eye relief is all you seek, then the urine of a human fetus is what you'll need—just don't mention it to the Food and Drug Administration.

The regulatory agency posted a public safety notification warning people not to use eye drops with such ingredients—products more akin to hocus-pocus than modern medicine.

The eye drops are thought to contain amniotic fluid, the clear liquid that surrounds and cushions a human fetus as it incubates in a womb. Generally, amniotic fluid contains a variety of maternal and fetal excretions and secretions, but after the 10th week of gestation, it is largely fetal urine, with fetal lung secretions being another significant

component.

Unapproved

Makers of these tinkly eyedrops claim they can treat eye conditions, namely dry eyes and inflammation. Any such biologic-based product claiming to cure or treat a condition is regulated by the FDA under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. As such, these products require an investigational new drug application (an IND) to be tested in humans and a full FDA approval before hitting the market.

This appears to have been news to at least two companies that the FDA sent warning letters to late last year. The companies, Regener-Eyes and M2 Biologics, were illegally selling unapproved eye drops, which the FDA said contained amniotic-fluid, to treat dry eyes.

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In fact, there is not a single amniotic-fluid eye drop product approved by the FDA, and any such product used under an IND requires patients to sign consent forms. Yet, the FDA is finding these products on the market, the regulator said in its notification.

“[M]anufacturers are marketing and distributing amniotic fluid eye drops to treat, mitigate, or cure diseases or conditions such as dry eye disease without the required premarket review and approval, raising potential significant safety concerns,” the agency warned.

Without the proper approvals and oversight, the agency noted that it does “not have information about their manufacture, and there are no assurances that the products are safe and effective for any disease or condition.”

And there’s a good chance that they aren’t effective. For

years, some researchers have touted the potential regenerative and healing properties of amniotic fluid for eye conditions. And for decades, ophthalmologists have used amniotic *membranes* for repairing the surface of the eye—with mixed results.

But, to date, only one clinical trial of amniotic fluid eye drops has been published—and it found the drops were ineffective. The trial, published just last month, was run by researchers at the Moran Eye Center at the University of Utah. They looked at whether processed amniotic fluid could speed recovery after a type of laser eye surgery called photorefractive keratectomy (PRK), which is used to treat common vision problems. The randomized, controlled trial involving 61 people found that amniotic fluid was no better than placebo.

Blurry products

It’s not a wild idea that amniotic components could help eyes. Amniotic membranes are thought to support eye surface repair because the fetal membrane has a similar cellular composition to the mucus membrane on the surface of the eye. Moreover, amniotic tissue and fluid can contain electrolytes, growth factors, enzymes, hormones, and immunoglobulins, which can help spur cellular repair. But with any donated biological material, there’s variation and the risk of inadvertently transferring pathogens; and with amniotic fluid, there’s the fact that it’s 98 percent water. In studies of amniotic membranes, researchers have come up with mixed results, with successes in pilot studies vanishing in larger randomized controlled trials.

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This apparently hasn’t stopped some people from making strong claims about the benefits of dripping amniotic fluid onto eyeballs. M2 Biologics claims its StimulEyes “regenerative eye solution” can soothe dry eyes with “natural anti-inflammatory

components.” The Georgia-based company’s website says that the eye drops, which run $229 for a one-month supply, are currently unavailable for sale.

Regener-Eyes, the other company called out by the FDA for selling amniotic-fluid eye drops, still appears to be selling eye drops via “eye care professionals.” However, sometime last year it scrubbed its website of details about what is in its eye drops. An Internet Archive version of its products page captured on May 19, 2022, shows that the Florida-based company promoted its eye drops as a “natural, biologic” that contained “cytokines, chemokines and growth factors such as VEGF, TGFβ1, TGFβ3, EGF, IL-1Ra , PDGF, ST2, bFGF, KGF, GDF11, HC-HA/PTX3 (Pentraxin 3) (hyaluronic acid), and Collagen Types I, III, IV, V.”

Its archived page on clinical studies noted publications on amniotic fluid and “amniotic derived therapies.” But, in terms of clinical studies of its own eye drops, the company listed only informal, vague documents, such as black-and-white pictures of individual patients’ eyes and a single graph of results from a patient survey, none of which is published in a scientific journal or peer-reviewed.

All of that is now gone. The website currently states that its eye drops are an “OTC Drug that is preservative free” and is “in compliance with all Federal regulatory laws.” It’s unclear if the company changed the formulation of the product or just changed its website. Regener-Eyes did not respond to emailed questions from Ars.

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