

From: OC GCP Questions
To: [REDACTED]
Subject: FW: Inquiry regarding regulations regarding adult stem cell transplantation in humans
Date: Sunday, April 13, 2014 11:25:00 AM

Good morning –

This is a general GCP mailbox. You will need to contact the Center for Biologics directly at the contact information below.

(800) 835-4709

(301) 827-1800

ocod@fda.hhs.gov

Kind regards,

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Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [Redacted]
Sent: Sunday, April 13, 2014 6:24 AM
To: OC GCP Questions
Subject: Inquiry regarding regulations regarding adult stem cell transplantation in humans

Dear Office of Good Clinical Practice,

For the reconstruction of the ocular surface following limbal stem cell deficiency, [redacted]. Because of change done recently to the contact lens surface, there was a need to coat the contact lenses with 0.1% gelatin for cell adhesion.

Recently I was asked to collaborate with a few medical centers in order to help patients who suffer from limbal stem cell deficiency.

I should state the cells are cultivated in the presence of fetal calf serum.

I wounded about the regulation regarding transplantation of adult [redacted].

1. **Should there be a problem using [redacted]?**
2. **Should there be a reason not to use [redacted] for the cultivation of the cells?**

In the article attached [redacted] feeder layer is authorized for use in the USA and other countries. In addition they have used fetal calf serum for the cultivation of the cells before transplantation like many other groups.

3. Should there be a reason to avoid using gelatin coating?

There are many products containing gelatin used for clinical proposes such as [redacted] and other devices.

It would be very helpful to understand what the regulation are regarding the use of the various components before going forward to the transplantation stage in humans.

Most Sincerely,

[Redacted]