From: OC GCP Questions
To: [redacted]
Subject: IRB review of study involving marketed spectacles
Date: Wednesday, March 16, 2016 6:36:20 AM

Good morning –

Not all research is FDA-regulated. Bifocals might be considered a device but you said the product has been previously sold in the US. You might want to contact the Center for Devices (CDRH) at DICE@fda.hhs.gov

Or you can contact OHRP --

Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Toll-Free Telephone within the United States: (866) 447-4777
Telephone: (240) 453-6900
Fax: (240) 453-6909
E-mail: OHRP@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: Tuesday, March 15, 2016 12:39 PM
To: OC GCP Questions
Subject: IRB review of study involving marketed spectacles

Good afternoon,

Our IRB has been contacted by a group contemplating a clinical trial of a bifocal spectacles product previously sold in the U.S. (it has not been produced for several years). Our IRB has not reviewed studies of spectacles in recent years and we are seeking guidance on the applicability of requirements for IRB review in this type of situation. Is there a resource to which we can refer to determine whether IRB review is required for a trial of this type of product? Thank you in advance for your consideration.

Kind regards,

[redacted]