



**U.S. FOOD & DRUG  
ADMINISTRATION**

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

Certificate No. CT:UQXW-WAJ6

Application Number: 1040-19

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Lions Eye Bank of West Central Ohio, located at 3309 Office Park Dr, Dayton, OH 45439, USA, manufactured and distributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):**

Product Name

Human Cornea

The product(s) described above and the establishment(s) where it is produced are subject to FDA jurisdiction and regulated solely under section 361 of the Public Health Service Act (PHS Act) and regulations promulgated thereunder. and regulations promulgated thereunder. The company listed above has certified to the FDA that the HCT/P meets the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

It is certified that the above listed HCT/P may be marketed in, and legally exported from, the United States of America at this time. The company listed above is subjected to periodic inspections. The last inspection showed that the plant(s) at that time, appeared to be in compliance with the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271.

Signature \_\_\_\_\_

Robert A. Sausville  
Director  
Division of Case Management  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research  
Food and Drug Administration

This certificate is valid from June 05, 2019 to June 04, 2021.

