

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 109 Holton Street Winchester, MA 01890 (781) 587-7500 Fax: (781) 587-7556		DATE(S) OF INSPECTION 12/10/2024-12/20/2024* FEI NUMBER 1000513310			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Christina A. Cooper, Director, Quality					
FIRM NAME CorneaGen - Boston		STREET ADDRESS 300 Bear Hill Rd Fl 2			
CITY, STATE, ZIP CODE, COUNTRY Waltham, MA 02451-1033		TYPE ESTABLISHMENT INSPECTED Human Tissue Establishment			
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.					
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Donors were not determined to be ineligible that had risk factors or clinical evidence of communicable disease agents. Specifically, your firm failed to determine ineligible donors identified as having risk factors or clinical evidence of the relevant communicable disease agent or disease, sepsis, for which screening is required. Representative donor examples follow however this is not an exhaustive list. a) The donor records, including the hospital medical records, available at your firm for Donor (b) (4), (b) (6), (b) (7)(C) showed the donor had documented clinical evidence and/or a diagnosis of sepsis. Both corneas from this donor were recovered on (b) (6), (b) (7)(C). Your firm determined the donor was eligible on (b) (6), (b) (7)(C). Both corneas were made available for distribution on (b) (6), (b) (7)(C), these were shipped on to be transplanted on (b) (6), (b) (7)(C). b) The donor records, including the hospital medical records, available at your firm for Donor (b) (4), (b) (6), (b) (7)(C) showed the donor had documented clinical evidence and/or a diagnosis of sepsis. Both corneas from this donor were recovered on (b) (6), (b) (7)(C). Your firm determined the donor eligible but the date the decision was made was not recorded by your firm. Both corneas were made available for distribution on (b) (6), (b) (7)(C), these were shipped on 12/07/2023 to be transplanted. c) The donor records, including the hospital medical records, available at your firm for Donor (b) (4), (b) (6), (b) (7)(C) showed that the donor had documented clinical evidence and/or a diagnosis of sepsis. Both corneas from this donor were recovered on (b) (6), (b) (7)(C). Your firm determined the donor eligible but the date the decision was made was not recorded by your firm. These corneas					
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Anthony N Onianwa, Investigator </td> <td style="width: 40%; border: none; vertical-align: top;"> Anthony N Onianwa Investigator Signed By: Anthony N. Onianwa - Date Signed: 12-20-2024 14:36:36 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Anthony N Onianwa, Investigator	Anthony N Onianwa Investigator Signed By: Anthony N. Onianwa - Date Signed: 12-20-2024 14:36:36 X
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were made available for distribution on (b) (6), (b) (7)(C), these were shipped on (b) (6), (b) (7)(C) to be transplanted. d) The donor records, including the hospital medical records, available at your firm for Donor (b) (4), (b) (6), (b) (7)(C) showed the donor had documented clinical evidence and/or diagnosis of sepsis. Both corneas were recovered from this donor on (b) (6), (b) (7)(C). Your firm determined the donor was eligible on (b) (6), (b) (7)(C). Both corneas were shipped on (b) (6), (b) (7)(C), these corneas were made available for distribution on 01/17/2024.					
OBSERVATION 2 HCT/Ps that were recovered from a donor for whom a donor eligibility determination has not been completed were made available for distribution. Specifically, a) The donor records, including the hospital medical records, available at your firm for Donor (b) (4), (b) (6), (b) (7)(C) showed the donor had documented clinical evidence and/or a diagnosis of sepsis. Both corneas from this donor were recovered on (b) (6), (b) (7)(C). Your firm determined the donor eligible but the date the decision was made was not recorded by your firm. Both corneas were made available for distribution on (b) (6), (b) (7)(C), these were shipped on 12/07/2023 to be transplanted. b) The donor records, including the hospital medical records, available at your firm for Donor (b) (4), (b) (6), (b) (7)(C) showed that the donor had documented clinical evidence and a diagnosis of sepsis. Both corneas from this donor were recovered on (b) (6), (b) (7)(C). Your firm determined the donor eligible but the date the decision was made was not recorded by your firm. These corneas were made available for distribution on (b) (6), (b) (7)(C), these were shipped on (b) (6), (b) (7)(C) to be transplanted.					
*DATES OF INSPECTION 12/10/2024(Tue), 12/11/2024(Wed), 12/12/2024(Thu), 12/13/2024(Fri), 12/20/2024(Fri)					
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FOOD AND DRUG ADMINISTRATION

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Christina A. Cooper, Director, Quality

FIRM NAME

CorneaGen - Boston

STREET ADDRESS

300 Bear Hill Rd Fl 2

CITY, STATE, ZIP CODE, COUNTRY

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TYPE ESTABLISHMENT INSPECTED

Human Tissue Establishment

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EMPLOYEE(S) SIGNATURE

Anthony N Onianwa, Investigator

Anthony N Onianwa
Investigator
Signed By: Anthony N. Onianwa -
Date Signed: 12-20-2024
14:36:36

X

DATE ISSUED

12/20/2024

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."