

FOOD AND DRUG ADMINISTRATION
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)
FEI: 3001518813

See Instructions for OMB Statement FORM APPROVED OMB No 0910-0543 Expiration Date 6/30/2020
2. REASON FOR SUBMISSION
a INITIAL REGISTRATION / LISTING VALIDATED FOR FDA USE ONLY
b ANNUAL REGISTRATION / LISTING VALIDATED BY FDA 26-FEB-2018
c X CHANGE IN INFORMATION DISTRICT New York
d INACTIVE PRINTED BY FDA 01-MAR-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
- a BLOOD FDA 2830 NO
 - b DEVICES FDA 2891 NO
 - c DRUG FDA 2656 NO

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
Lions Eye Bank for Long Island

Northwell Health
900 Franklin Avenue
Valley Stream, New York 11580

- a PHONE 516-256-6990 EXT
- b SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO)
- c TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)
Lions Eye Bank for Long Island
Attn: Kristen Laino
Northwell Health
900 Franklin Avenue
Valley Stream, New York 11580

- a PHONE 516-256-6990 EXT
- 7. ENTER CORRECTIONS TO ITEM 6 b PHONE

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE
a E-MAIL
a TYPED NAME Kristen Laino

- b E-MAIL klaino1@northwell.edu
- c TITLE Technical Supervisor

FORM FDA - 3356 (7/17)

PART II - PRODUCT INFORMATION
10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions							14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store	Label	
a Bone								
b Cartilage								
c Cornea	X	X	X	X	X	X	X	X
d Dura Mater								

11. HCT/PS DESCRIBED IN 21 CFR 1271.10
12. HCT/PS REGULATED AS MEDICAL DEVICES
13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS

Types of HCT / Ps	SIP	
	Directed	Anonymous
i Oocyte		
j Pericardium		
k Peripheral Blood Stem		
l Sclera	X	X
m Semen		
n Skin		
o Somatic Cell Therapy Products		
p Tendon		
q Umbilical Cord Blood		
r Vascular Graft		
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d DATE 26-FEB-2018