DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

FEI: 3008769422

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2023
Last Registration Receipt Date: 11/23/2022
Summary Report Print Date: 12/01/2022

No

Legal Name and Location:

Advanced Biologics, LLC 1905 Aston Suite 101

USA

Jesse A

Carlsbad, California 92008

Ext.:

Phone: 800-272-0267

Reporting Official:

Jesse Adawag, Director, Quality & Regulatory

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LISA

Phone: 800-272-0267 Ext. 704 jadawag@advancedbiologics.com

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

	Donor Type(s)	Establishment Functions										
HCT/P(s)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel												
Bone							Х		Х			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							Х					
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Annual registration renewal for FEI: 3008769422.								
Proprietary Name(s):	Bone	OsteoAMP, OsseoGEN, OsteoFactor						

3008769422

FEI:

Legal Name:

Advanced Biologics, LLC