AUGMENT® Bone Graft Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Biomimetic Therapeutics, LLC
Russ Pagano, Ph.D.
Vice President, Clinical and Regulatory Affairs
389 Nichol Mill Lane
Franklin, Tennessee 37067

September 1, 2015

Re: P100006
Trade/Device Name: Augment® Bone Graft
Filed: May 7, 2010
Amended: May 7, May 13, November 19, 2010; April 15, August 5, 2011; June 15, July 2, September 13, 2012; September 3, September 5, 2013; February 7, March 31, April 29, June 24, October 31, November 4, November 19, 2014; February 18, and April 9, 2015
Procode: NOX

Dear Dr. Pagano:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for Augment® Bone Graft. This device is indicated for use as an alternative to autograft in arthrodesis (i.e., surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

CONFIDENTIAL INFORMATION REDACTED

AUGMENT® Bone Graft Approval Letter

If you have any questions concerning this approval order, please contact Sarah Brittain at 240-402-3141 or Sarah.Brittain@fda.hhs.gov.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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AUGMENT® Injectable Approval Letter

U.S. FOOD & DRUG ADMINISTRATION

June 12, 2018

BioMimetic Therapeutics, LLC
% Jeanne S. Warner, BSN, RN, MS
Director, Regulatory Affairs and Quality Assurance
389 Nichol Mill Lane
Franklin, Tennessee 37067

Re: P100006/S005
Trade Name: AUGMENT® Injectable
Filed: December 21, 2016
Amended: January 31, April 5, September 25 and December 21, 2017
Product Code: NOX

Dear Ms. Warner:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for AUGMENT® Injectable. This device is indicated for use as an alternative to autograft in arthrodesis (i.e., surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material. We are pleased to inform you that the PMA supplement is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that this restriction on sale and distribution is necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 36 months. AUGMENT® Injectable must be stored at refrigerated temperature (2-8°C, 36-46°F).

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AUGMENT® Injectable Approval Letter

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Aric Kaiser at 301-796-6425 or Aric.Kaiser@fda.hhs.gov.

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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