Allergen Medical 5/29/15

Department of Health and Human Services

Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

WARNING LETTER

May 29, 2015

Samir Paliwal
Quality Assurance Director
Allergan
200 Boston Avenue, Ste. 3700
Medford, MD 02155

Re: Surgical Mesh
Refer to CMS # 459702

Dear Mr. Paliwal:

The United States Food and Drug Administration (FDA) has learned that your firm is marketing SERI Surgical Scaffold in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, 21 U.S.C.§ 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

FDA has reviewed your firm's website, http://www.seri.com and determined that the SERI Surgical Scaffold is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C.§ 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. The device is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution this device with major changes or modifications to the intended use without submitting a new premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(ii).

Specifically, the SERI Surgical Scaffold was cleared under K123128 with the following indications for use as a transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction. However, your firm's promotion of the device provides evidence that the device is intended for breast surgery applications, which would constitute a major change or modification to its intended use, for which your firm lacks clearance or approval. Examples include:

"Specific procedures which may benefit from the use of SERI Surgical Scaffold for soft tissue support and repair include:

- Breast revision surgery
- Mastopexy with or without augmentation
- Breast reductions ...
- ... Muscle flap reinforcement"

These indications fall outside of your firm's intended use because surgical mesh has not been cleared or approved for use in breast reconstruction using a tissue expander or implant. In addition, the specific breast reconstruction surgery indication changes the intended use of a surgical mesh cleared with a general soft tissue reinforcement indication regulated by 21 CFR 878.3300.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Our office requests that Allergan immediately cease activities that result in the

misbranding or adulteration of the SERI Surgical Scaffold such as the commercial distribution of the device for the uses discussed above.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) your firm has taken. If your firm 's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed.

Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
White Oak Building 66, Rm 2609
10903 New Hampshire Ave.
Silver Spring, MD 20993

Refer to the identification number CMS # 459704 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Ms. LaShanda Long at 301-796-5770 or 301-847-8137 (fax).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Sincerely yours,
/S/
Jan Welch, MHS, MT (ASCP) SBB

Acting Director
Office of Compliance
Center for Devices and
Radiological Health

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Page Last Updated: 06/04/2015
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U.S. Food and Drug Administration
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Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

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