DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAR 21 2014

Reginald Burgess
% Garrett Skelly, ESQ
160 Centennial Way Ste 21
Tustin, CA 92780

Re: Citizen Petition – Docket Number FDA-2013-P-0949

Dear Mr. Burgess,

This letter responds to the above referenced citizen petition that you submitted to the Food and Drug Administration (FDA). Your petition requests that FDA amend the clearance of the Otto Bock C-Leg, submitted under 510(k) premarket notification K991590, to include both prescription and over-the-counter use. Your petition further requests that all prosthetic devices regulated under Title 21 of the Code of Federal Regulations (CFR) 890.3420 and 890.3500 be labeled for over-the-counter use.

As outlined below, through regulations set forth in Title 21 of the Code of Federal Regulations, your request to label these devices for over-the-counter use is a change to the indications for use of the device and must be submitted as part of a premarket notification (510(k)) by the owner or operator of the establishment that has the rights to manufacture and/or distribute the device. Therefore, your request is not within the scope of FDA's citizen petition procedures and the Agency denies your request.

A. Changes to exempt devices that require a premarket notification

External limb prosthetic components are classified under 21 CFR 890.3420 as class I (general controls) medical devices and external assembled lower limb prostheses are classified under 21 CFR 890.3500 as class II (special controls) medical devices. As described in both of these regulations, these devices are exempt from the premarket notification procedures in subpart E of 21 CFR 807, subject to the limitations in 890.9. The limitations of exemptions in 21 CFR 890.9 state that a 510(k) is required if "*(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or (b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device...*"

K991590 was cleared for marketing with indications for prescription use only[1] and with labeling that included the prescription use statement.[2] Although other devices with the

[1] http://www.accessdata.fda.gov/cdrh_docs/pdf/K991590.pdf
[2] 21 CFR 801.109(b)(1)

same intended use and the same fundamental scientific technology would be exempt from the 510(k) requirements, 21 CFR 890.9 requires a 510(k) submission for a request to add 'over-the-counter use' to the indications for use of a device that was previously for 'prescription use only'. Therefore, the Agency cannot consider your request through a citizen petition.

B. Procedure for requesting a change in intended use

In addition to the criteria outlined in the limitations of exemptions, 21 CFR 807.81(a)(3)(ii) also states that a 510(k) is required for "*a major change or modification in the intended use of the device.*" As clarified in the guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device" issued on January 10, 1997[3], and consistent with the criteria in 21 CFR 890.9 identified above, the Agency considers the addition of 'over-the-counter use' to the indications for use of a device that was previously for 'prescription use only' as a modification that requires a 510(k) submission. Therefore, the Agency cannot consider your request through a citizen petition.

C. Prescription Use Restriction

In your petition, you stated that "external prosthetic devices have NEVER met the definition for restriction to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority, of section 515(d)(I)(B)(ii) of the act." However, section 515(d)(I)(B)(ii) is specific to class III devices that are subject to premarket approval (PMA) and is not applicable to external prosthetic devices. Nonetheless, prescription-use restrictions are a type of general control authorized under section 520(e) and defined as a general control in section 513(a)(1)(A)(i) of the FD&C Act. External prosthetic devices as a class of devices are not restricted by regulation to prescription use. Individual devices may be restricted to prescription use as determined by the Agency under the conditions set forth in 21 CFR 801.109. However, as outlined above, this determination requires a 510(k) submission.

D. Who may submit a premarket notification

Although the Agency would consider a modification of the indications for use of the Otto Bock C-Leg through the 510(k) process, this request must be submitted by Otto Bock or their authorized representative. 21 CFR 807.81(a) clarifies that the 510(k) submitter should be the "*person who is required to register his establishment pursuant to 807.20*," i.e., "*any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use.*"[4] Because Otto Bock was the original submitter of K991590, any requests to modify the indications for use should be submitted to the Agency by Otto Bock or any persons to whom they have transferred ownership of the 510(k). Based on the information in your petition, your

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[3] http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080235.htm

[4] 21 CFR 807.20(a); see also 21 CFR 807.3(d)

relationship to Otto Bock is as an end-user of the C-Leg device. As a result, you do not constitute a person engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device and, therefore, are not eligible to submit a 510(k) for that device.

E. Conclusion

For the reasons discussed above, the actions requested in your petition require a premarket notification (510(k)) submission and are not within the scope of the citizen petition procedures. Additionally, any such 510(k) must be submitted by the owner or operator of the establishment that has the rights to manufacture and/or distribute the device and not by an end user. Therefore, the Agency denies your request.

If you have any questions, please contact Mr. Madhusoodana Nambiar by e-mail at madhusoodana.nambiar@fda.hhs.gov or 301-796-5837.

Sincerely yours,

Nancy K. Stade, JD
Deputy Director for Policy
Center for Devices and
Radiological Health