DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 0 2 2014

Reginald Burgess
% Garrett Skelly, ESQ
160 Centennial Way, Suite 21
Tustin, California 92780

Re: Citizen Petition – Docket Number FDA-2013-P-1080

Dear Mr. Burgess:

This letter responds to the above referenced citizen petition dated August 29, 2013, and filed with the Food and Drug Administration (FDA) on September 4, 2013. In the Petition, you request that the FDA Commissioner amend Title 21 of the Code of Federal Regulations (CFR) 820.198, Complaint files, to add a section "(a)(4)" to require specific actions for complaint handling for devices regulated under 21 CFR 890.3420, External limb prosthetic component, or 21 CFR 890.3500, External assembled lower limb prosthesis.

We have reviewed the information in your submission and, in accordance with 21 CFR 10.30(e)(3), address your request in this response. For the reasons explained below, we deny your petition.

I. Request for Action

In your petition, you request that the FDA Commissioner amend Title 21 of the Code of Federal Regulations (CFR) 820.198 to add a section "(a)(4)" to state:

"(4) Complaints or requests which involve requests direct or indirect from end user consumers for information for, or parts for, any item the manufacturer has manufactured under any FDA regulation, 510K exempt or not, under sections 21 CFR 890.3420 or 890.3500 for external prosthetic items or parts not available anywhere but from the manufacturer shall be addressed directly to the complainant and shall not be delayed or deferred. The manufacturer may not rely on in house distribution models or programs as any restriction to deny access to the parts or information requested to keep the subject item operating in a safe manner, unless there is complete and accurate evidence the item is completely malfunctioning where 21 CFR 820.200 would reasonably apply. The manufacturer shall provide all materials and instructions to the owner to operate or repair the device themselves or program or re-program the item as need be unless it is a restricted item under 21 CFR 81.109, and this provision shall apply whether the item is under warranty or not. If the owner seeks to do the repair work themselves, unless the manufacturer can show a legally sufficient business reason – of a 'fundamental alteration' or 'undue burden' or 'direct threat' reason the owner cannot do said work, the manufacturer is to provide by sale of the parts needed at proper and reasonable costs the parts and/or instructions to the owner/wearer and document same under the provisions of 22 CFR 820.200 as a 'service' to

the item in question and said records shall be kept as such. This requirement does not apply to resellers, distributors or end use manufacturers."

II. Decision Summary

Your request involves a request to amend a section of Title 21 of the Code of Federal Regulations Part 820 – Quality System Regulation. 21 CFR 820.1(a), Scope, states in part, that *"The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged."* As such, Part 820 contains basic requirements which apply to manufacturers across the full spectrum of medical devices.

The Summary published for Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation[1], states in part, *"This regulation sets forth the framework for device manufacturers to follow and gives them greater flexibility in achieving quality requirements."* In addition, I. Background, of the Final Rule, states in part, *"The agency's final rule embraces the same "umbrella" approach to the CGMP regulation that is the underpinning of the original CGMP regulation. Because this regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures to fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device. FDA has made changes to the proposed regulation and the Working Draft, as the final rule evidences, to provide manufacturers with even greater flexibility in achieving the quality requirements."*[2] Furthermore, though not specific to your request, the Background notes that in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), the Supreme Court, *"noted that CGMP requirements are general rather than "specific requirements applicable to a particular device."*

In your petition, you have requested the addition of language specific to a particular device type, which prescribes how a manufacturer must respond to requests and/or complaints related to a user's desire to perform their own maintenance or repairs to a lower limb prosthesis. This degree of specificity is not in keeping with the general requirements of 21 CFR Part 820 – Quality System Regulation.

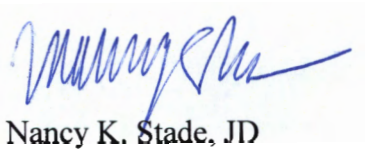
---

[1] Federal Register, Vol 61, No 195, Monday, October 7, 1996, Rules and Regulations, 52602
[2] Federal Register, Vol 61, No 195, Monday, October 7, 1996, Rules and Regulations, 52603

Within the "Statement of grounds" in your petition, you provide information related to your prior petition to the FDA, FDA-2013-P-0949, as the basis for the action requested in this petition. Please refer to the response dated, March 21, 2014, for the Agency's position on this matter. Please note that both prescription and over-the-counter medical devices are subject to 21 CFR Part 820, as applicable.

For the reasons noted above, the agency denies your request. If you have any questions, please contact Mr. Madhusoodana Nambiar by email at madhusoodana.nambiar@fda.hhs.gov or by phone at 301-796-5837.

Sincerely yours,



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