DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

AUG 28 2014

Mr. Reginald Burgess
% Garrett Skelly, ESQ
160 Centennial Way Ste 21
Tustin, California 92780

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

Dear Mr. Burgess,

This is an interim response to the petition dated April 2, 2014, filed by the Food and Drug Administration (FDA) on April 8, 2014. In the petition, you requested FDA to reconsider the petition submitted on August 6, 2013, to amend clearances of all external prosthetic devices regulated under Title 21 of the Code of Federal Regulations (CFR) 21 CFR 890.3420 and 21 CFR 890.3500 to read as both "prescription" and "over the counter use" in particular for the Otto Bock C-Leg, submitted under 510(k) premarket notification K991590. Your petition further requests that FDA revoke the clearance of Otto Bock C-Leg, submitted under 510(k) premarket notification K991590 as per the limitations of exemption in 21 CFR 890.9.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Mr. Madhusoodana Nambiar of our Regulations Staff at (301) 796-5837.

Sincerely yours,

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