DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

FEB 2 4 2014

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

Re: Citizen Petition – Docket Number FDA-2013-P-1080/CP1

Dear Mr. Burgess:

This is an interim response to the petition dated August 29, 2013, filed by the Food and Drug Administration (FDA) on September 4, 2013. In the petition, you requested FDA to amend 21 CFR 820.198 to add section "(a)(4)" to require manufacturers to provide information or parts for external prosthetic devices under sections 21 CFR 890.3420 or 21 CFR 890.3500 directly to consumers upon request by the consumer.

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 Director for Policy
Center for Devices and
Radiological Health