



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR 26 2014

Mr. Kevin Boulton  
c/o 7421 Douglas Blvd, #410  
Douglasville, GA 30134

Re: Citizen's Petition – Docket Number FDA-2013-P-1297

Dear Mr. Boulton:

This is an interim response to your citizen petition dated September 26, 2013, which was filed by the Food and Drug Administration (FDA) on September 30, 2013. In your petition you, on behalf of yourself and representing the families Harmony's Candles, request the Commissioner of Food and Drug issue a declaratory order that Harmony Cone Ear Candles (HCEC) are not medical devices under Section 201(h) of the Food Drug and Cosmetic Act (FDCA). Further, you request a public hearing on the issues presented in your petition. Finally, you ask the Commissioner of Food and Drug temporarily stay any regulatory enforcement action against any HCEC manufacturer, distributor or seller during the pendency of this petition.

FDA has been unable to reach a decision on your citizen 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 Loretta Chi of our Regulations Staff at (301)796-5847.

Sincerely yours,

Nancy Stadel  
Deputy Director for Policy  
Center for Devices  
and Radiological Health