



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

October 25, 2013

Kevin Boulton  
Harmony Cone Ear Candles  
c/o 7421 Douglas Blvd, #410  
Douglasville, GA 30134

Dear Mr. Boulton:

Your petition to the Food and Drug Administration requesting the Agency to issue a declaratory order finding that HCEC, as defined in your petition, are not "devices" under FDCA § 201(h), was received by this office on 9/30/2013. It was assigned docket number FDA-2013-P-1297/CP1, and it was filed on 10/25/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Karen Kennard".

Karen Kennard  
Director  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)