DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

MAR 26 2014

Ms. Clarissa Clarke
101 Alston Avenue
New Haven, CT 06515

Re: Citizen Petition – Docket Number FDA-2013-P-1611-0001

Dear Ms. Clarke:

This is an interim response to the petition dated November 26, 2013, filed by the Food and Drug Administration (FDA) on December 2, 2013. In the petition, you requested FDA issue special controls for Tooth Shade Resin Material (21 CFR 872.3690) and for Ultraviolet Activator for Polymerization devices (21 CFR 872.6070) based on challenges you have identified concerning effective use of these devices.

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 Erica Blake of our Regulations Staff at (301) 796-3999.

Sincerely yours,

Nancy Stade, J.D.
Deputy Director for Policy
Center for Devices and
Radiological Health