DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 23, 2013

FILE COPY

Clarissa Clarke
(b) (6)
[redacted]

Re: This is a correction to the acknowledgement letter of 12/12/2013

Dear Ms. Clarke:

Your petition to the Food and Drug Administration requesting the Agency to amend two regulations within The Code of Federal Regulations, Title 21 - Food and Drugs, Chapter 1, Supchapter H- Medical Devices, Part 872- Dental Devices (Subpart D-Prosthetic Devices 872.3690 - Tooth Shade Resin Material and Subpart G-Miscellaneous Devices 872.6070 - Ultraviolet Activator for Polymerization) to include special controls guidance, was received by this office on 12/2/2013. It was assigned docket number FDA-2013-P-1611/CP1, and it was filed on 12/12/2013. 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,

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