July 18, 2024

Clarissa Clarke
[redacted]

Re: Citizen Petition – Docket No. FDA-2013-P-1611: Final Response

Dear Ms. Clarke:

This Final Response is to the above referenced citizen petition dated November 26, 2013, and filed with the Food and Drug Administration ("FDA" or "Agency") on December 2, 2013 (with a technical amendment to the petition dated March 20, 2014, and filed with the FDA on March 31, 2014). In your citizen petition you requested that FDA amend the regulations for tooth shade resin material (21 C.F.R. § 872.3690) (hereinafter, "tooth shade resin") and ultraviolet activator for polymerization (21 C.F.R. § 872.6070) (hereinafter, "dental curing light") to add the special controls described below. FDA sent you an Interim Response to the petition by mail on March 26, 2014.

In accordance with 21 CFR 10.30(e), and for the reasons set forth below, we are denying your request. However, we note that FDA recently issued two draft guidance documents for these device types on July 12, 2024, "Dental Composite Resin Devices - Premarket Notification (510(k)) Submissions"[1] (FDA-2024-D-2511) (hereinafter "Dental Composite Resin draft guidance") and "Dental Curing Lights - Premarket Notification (510(k)) Submissions" [2] (FDA-2024-D-2512) (hereinafter "Dental Curing Lights draft guidance") (together, the "Draft Guidances"). The Draft Guidances, when finalized, will provide recommendations that reflect current review practices and are intended to promote consistency and facilitate efficient review of submissions for these device types, and which we believe address many of the concerns you identified.

I. Requested Action

Your petition requests that FDA amend the following two regulations:

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-composite-resin-devices-premarket-notification-510k-submissions
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-curing-lights-premarket-notification-510k-submissions

- 21 CFR 872.3690 - Tooth shade resin material. Tooth shade resin material is a device composed of materials such as bisphenol-A glycidyl methacrylate (Bis-GMA) intended to restore carious lesions or structural defects in teeth.

- 21 CFR 872.6070 - Ultraviolet activator for polymerization. An ultraviolet activator for polymerization is a device that produces ultraviolet radiation intended to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of light through a rod.

Tooth shade resin is a type of dental composite resin currently regulated as a class II device, product code EBF. Dental curing lights are currently regulated as class II devices, product codes EBZ and QNF. Devices with product code QNF, Laser Activator for Polymerization, are not within the scope of this Final Response. Although the petition refers to devices under § 872.6070, at the time the petition was filed with FDA there were no laser devices classified under that regulation. As such, we interpret the petition as a request to establish special controls for dental curing lights with technologies existing at the time the petition was filed, which fall under product code EBZ. We also note that devices with product code QNF have additional requirements as laser products as compared to the subject devices with product code EBZ.

Tooth shade resin and dental curing lights are interdependent because dental curing lights are needed to set (cure) photo-curing tooth shade resin, as well as other photo-curing dental restorative resins. Both device types require 510(k) submission and clearance to be legally marketed and are not 510(k) exempt under section 510(m)(2) of the FD&C Act.

Specifically, your petition requests the following actions by FDA:

> "The requested action to 872.3690 is to include Special Controls to expand tooth shade resin material (e.g., resin based composites or RBCs) properties and performance reporting to include the:
>
> 1. Material properties and performance when it has received the manufacturer's minimum level of light delivery and clinically relevant levels of light delivery; and
>
> 2. The specific amount and spectral makeup of the energy required to accurately polymerize each brand and shade of material.
>
> The requested action to 872.6070 is to include Special Controls to expand polymerization activator (i.e., dental curing light) reporting to provide dentists with:
>
> 1. Information as to how their curing light will perform when used intra-orally (e.g., when used at distances up to 10 mm between the light tip and the surface of the tooth shade resin material, and in terms of whether the beam of light is sufficiently broad and homogenous to cure an entire restoration);

2. Information as to the intra-oral heating effects of the curing light, both in terms of surface (affecting soft tissues) and pulpal temperature increases; and

3. Instructions to verify the output of their dental curing lights period[i]cally to ensure they are functioning as required."[3]

We interpret each request in your petition as asking that the Agency amend the regulations to require certain information in the labeling for each device type.

II. Regulatory Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360c) establishes three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I (general controls), class II (special controls and general controls), and class III (premarket approval and general controls). Section 513(a)(1)(B) of the FD&C Act (21 U.S.C. § 360c(a)(1)(B)) defines class II devices as devices for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (*see also* 21 CFR § 860.3). Thus, FDA can establish labeling requirements as special controls if it determines such is necessary to provide reasonable assurance of safety and effectiveness. FDA has not previously established labeling requirements as a special control for tooth shade resins or dental curing lights.

Even in the absence of special controls for labeling, class II devices are subject to general controls, including the requirement that device labeling include adequate directions for use and adequate warnings (section 502(f)(1) of the FD&C Act). 21 CFR 801.109 exempts a prescription device from the general control requiring adequate directions for use by lay persons under section 502(f)(1) if, among other requirements, its labeling bears information for use under which practitioners can use the device safely and for the purpose for which it is intended (hereinafter, the "801 labeling requirements").[4] To assist sponsors in preparing labeling that satisfies the 801 labeling requirements, FDA may provide suggestions for a particular device in guidance to industry in the form of labeling recommendations.

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[3] Citizen petition available at https://www.regulations.gov/search?filter=FDA-2013-P-1611.

[4] 21 CFR 801.109(c) ("Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented").

III. Decision Summary

As noted above, your petition requests that FDA amend the regulations for tooth shade resin and dental curing lights to establish special controls in the form of several new labeling requirements. These mandatory special controls, if promulgated, would impose new requirements that affected manufacturers must meet to legally market their devices.

In support of your request, the petition asserts that when tooth shade resin is incompletely polymerized there are increasing deleterious effects and that cytotoxicity and decreased performance are associated with inadequate curing. Your petition indicates that inadequate curing occurs when insufficient energy is delivered to the resin and cytotoxicity risk increases when monomers and additives are incompletely polymerized. Your petition also identifies several risks associated with dental curing lights including: (i) thermal risks; (ii) risks of improper curing of targeted devices due to beam attenuation, beam heterogeneity, light maintenance, and associated radiometer inaccuracies; and (iii) uncertainties about curing times and depth of cure.

FDA recognizes the risks associated with improper curing of dental composite resins, including tooth shade resin, and agrees that it is important for this device type to be cured properly to achieve its intended effect. However, to the extent that your petition is asking the Agency to require specific labeling as a special control, FDA is denying your petition. In making this determination, FDA reviewed the information contained in your petition, including the supporting documents you cited, and other information available since the petition was filed. As part of the review, FDA analyzed medical device reports (MDRs) submitted to the Manufacturer and User Facility Device Experience (MAUDE) database for product codes EBF and EBZ from January 1, 2012 to May 26, 2022. The analysis found no failure modes consistently reported or trends identified during that time period that would raise additional concerns of safety or effectiveness for those product codes. In addition, there is no significant recall history for either of these product codes during that time period. Taken together with other evidence available to the Agency, these facts demonstrate that the Agency's existing 510(k) review practices described in the final guidance documents "Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions",[5] issued in 2005, and "Dental Curing Lights – Premarket Notification [510(k)]",[6] issued in 2006, including labeling recommendations aimed at assisting sponsors to satisfy the part 801 labeling requirements, effectively balance the risks and benefits of these device types and provide reasonable assurance of safety and effectiveness. As such, the requested special controls are not necessary at this time to provide for a reasonable assurance of safety and effectiveness for these device types.

[5] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-composite-resin-devices-premarket-notification-510k-submissions-guidance-industry-and-fda

[6] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-curing-lights-premarket-notification-510k

Moreover, the 2024 Draft Guidances, which cover tooth shade resins and dental curing lights, among other things, propose additional labeling recommendations to assist sponsors when preparing product labeling that satisfies current regulatory requirements and update performance testing recommendations to reflect FDA's current review practices for these device types.

Specifically, consistent with the concerns you expressed in the citizen petition, the Draft Guidances propose the following recommendations, among others:

- In the Dental Composite Resin draft guidance:
    - Performance testing include depth of cure (mm) for normal mode at 10 seconds on a representative or "universal" shade; and
    - Curing time(s) reported on the labeling include time(s) for all the different resin shades (sec).
- In the Dental Curing Lights draft guidance:
    - Labeling include recommended distance (mm) and angle (degrees) from the tooth surface;
    - Performance testing include a thermal image or beam profiler of cross section of the light guide tip at maximum radiant exitance showing relative "hot" and "cold" spots across lateral surface of the device light guide tip;
    - Performance testing include depth of cure (mm) on a representative, legally marketed dental restorative resin sample after a clinically relevant curing time (FDA recommends 10 seconds and that you identify the dental restorative resin that was tested);
    - Performance testing identify the maximum temperature (°C) of the body of the device and at 2 mm from the distal end of the device under normal and single fault conditions when operated under the worst-case scenario, i.e., for the highest radiant exposure (J/cm2), and that data demonstrate that during normal and single fault conditions, the temperature generated by the device remains safe for both patient and practitioner; and
    - Labeling include instructions on how to periodically check irradiance output.

FDA is currently seeking public comment on the Draft Guidances. The public is urged to submit written comments on the Draft Guidances by September 10, 2024, to ensure that the Agency considers the comment on the draft guidance before it begins work on the final version of the guidance, but comments may be submitted at any time. You can access the Draft Guidances and background documents and read the comments submitted by others, as well as submit your own comments, at regulations.gov, using the docket numbers listed on page 1 above. We encourage you, as well as others, to participate and share insights regarding the Draft Guidances. While we are denying your specific request, we appreciate the information provided and note that the proposed recommendations in the Draft Guidances, when finalized, may address some of the concerns discussed in your petition. Moreover, the Draft Guidances, when finalized, will clarify the Agency's current thinking regarding 510(k)s for these two device types.

With respect to other concerns expressed in your petition, the Agency believes that the requested labeling requirements in your petition are not necessary at this time to provide for a reasonable assurance of safety and efficacy for these device types and may not provide useful information to practitioners. For instance, for tooth shade resins, FDA disagrees that manufacturers also should be required to report material properties and performance for minimum or "worst case" energy levels. Such a requirement may lead to use of non-standardized methodologies to determine material properties at minimal levels of curing, making it difficult to compare devices and for practitioners to determine acceptability of the device. In addition, FDA believes most practitioners already are aware that property and performance values for these and other dental device types typically are derived from bench tests in accordance with consensus standards that assume ideal curing conditions, such as FDA-recognized International Organization for Standardization (ISO) 4049: *Dentistry — Polymer-based restorative materials.* [7] Labeling that reflects use of the standard methodology is more useful for practitioners as a baseline and allows for direct comparison between devices. For dental curing lights, based upon the information available to the Agency, we do not believe requiring intra-oral performance testing for beam attenuation on the device labeling is necessary at this time to provide a reasonable assurance of safety and effectiveness of the device or would provide useful information to practitioners as the device is intended to be used at a fixed distance (e.g., 2mm) from the irradiated surface. When used at a fixed distance, beam intensity will be constant. Moreover, as indicated above, during our review we did not identify any consistent adverse event reporting or trends that would necessitate establishing a special control to require a warning about specific types of thermal hazards in addition to FDA's current recommendation to include a warning about thermal hazards consistent with 801 labeling requirements. The current applicable laws and requirements, as well as the Agency's current 510(k) review practices and recommendations effectively balance the risks and benefits associated with this concern and provide for a reasonable assurance of safety and effectiveness of the device types.

Your petition also expresses concerns that dental practitioners use curing times other than those recommended by dental composite resin manufacturers. Given the absence of signals from the MAUDE data and other information available to the Agency, we are not aware of any issues related to curing time and, as such, additional special controls to address this issue are similarly not necessary. Finally, your petition makes reference to reports that indicate dental composite resins have an average replacement time of 5.7 years due to secondary decay and fracture of the restoration. In addition, you claim that second restoration is invariably larger and ultimately can lead to an escalation of the intensity and cost of subsequent care. FDA agrees there are adverse health and economic impacts for patients that need revisional surgery to replace composite restorations that have not been properly placed. However, as noted earlier, FDA believes the 510(k) review practices described in 2005 and 2006 guidance documents referenced above effectively balance the risks and benefits of dental composite resins and dental curing lights and provide reasonable assurance of safety and effectiveness and that special controls are not needed. Moreover, the recommendations in the Dental Curing Lights draft guidance and the Dental

[7] For current versions of FDA-recognized consensus standards, see the FDA Recognized Consensus Standards Database Web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

Composite Resin draft guidance, when finalized, also can continue to help manufacturers and dental practitioners minimize these impacts.

V. Conclusion

For the reasons stated above, FDA denies your petition, noting that you may submit public comments to the above referenced docket of the Draft Guidances. If you have any questions about this response, please contact Patricia Kaufman at patricia.kaufman@fda.hhs.gov.

Sincerely,

Ellen J. Flannery -S Digitally signed by Ellen J. Flannery -S
Date: 2024.07.18 09:25:15 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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