March 20, 2014

2014 MAR 31 P 3:06

Division of Dockets Management,
Food and Drug Administration,
Department of Health and Human Services,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

Re: Docket Number FDA-2013-P-1611-0001

To Whom It May Concern:

On November 26, 2013 I submitted a Citizen's Petition that included an incorrect reference on the first page. Attached is a letter that corrects that error.

This error was brought to my attention by Erica Blake at the FDA (301-796-3999).

With thanks,

Clarissa Clarke
[redacted]

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Department of Health and Human Services,
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To Whom It May Concern:

Re: Citizen Petition (Docket Number FDA-2013-P-1611-0001 Please note that this is a corrected version of a Petition sent on November 26, 2013 and it includes a corrected reference to 872.6070 below)

The undersigned submits this petition under Federal Food, Drug, and Cosmetic Act, Subchapter A (General), Part 10 (Administrative Practices and Procedures), Subpart B (General Administrative Procedures), Section 10.20 (Citizen Petition) to request the Commissioner of Food and Drugs to amend two regulations within The Code of Federal Regulations, Title 21--Food and Drugs, Chapter 1, Subchapter H--Medical Devices, Part 872--Dental Devices.

Action Requested

The specific request of this petition is to amend the following to include Special Controls Guidance:

- **Subpart D--Prosthetic Devices § 872.3690 - Tooth shade resin material.**
  (a) Identification. 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.
  (b) Classification. Class II.

- **Subpart G--Miscellaneous Devices § 872.6070 - Ultraviolet activator for polymerization.**
  (a) Identification. 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.
  (b) Classification. Class II.

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 homogeneous 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 periodocally to ensure they are functioning as required.

Statement of Grounds

These two devices are interdependent. Polymerization activators are used to polymerize (e.g., cure or harden) tooth shade resin materials intra-orally. The top surface of tooth shade dental materials becomes hard within the first second(s) of polymerization, but the surface hardness tells the dentist nothing of the degree of cure immediately below the surface. As a result, the dentist has no way to physically assess the degree of cure.

When tooth shade resin material is incompletely polymerized there are increasing deleterious effects. These effects are well documented in the literature, and most recently in an American Dental Association Professional Product Review article in July 2013 (Bargi N, Ernst CP, Ferracane JL, Price RBT, Rueggeberg FA, Shortall A, Strassler HE, Watts DC. Effective Use of Dental Curing Lights: A Guide for the Dental Practitioner). The following is an excerpt from the article:

> *Almost every day, dentists see resin-based composite (RBC) restorations that have signs of margin chipping or breakdown, bulk fracture, bulk and marginal discoloration, loss of anatomical form, lack of retention, or secondary caries. There is considerable evidence that delivering inadequate energy to the restoration will result in a restoration that has less than optimal properties and poor clinical performance. Thus, it is important to keep a few basic facts in mind.*
>
> *The most common reasons cited for replacement of light-activated restorations are secondary caries and restoration fracture. Other reasons include marginal breakdown and staining, wear, discoloration, pulpal death, and tooth fracture. It is*

well established that reduced levels of resin polymerization caused by delivering an inadequate amount of light, or light at the wrong wavelengths, will adversely affect many RBC properties.

The combined use of tooth shade resin materials (i.e., resin-based composites or RBCs) and polymerization activators has become increasingly complex. The variables that need to be managed by dentists have increased over the past decade, some as a direct result of market innovations. For example:

- **New photo initiator systems** in tooth shade resin materials, specifically designed to accommodate consumer demands for whiter shades;
- **New types of light sources** (e.g., LED) in dental curing lights;
- **Turbo light guides** that focus the intensity in a small area very close to the light tip, but result in a dramatic drop in intensity as the distance between the light tip and the surface of the resin material increases to a clinically relevant distance (e.g., 6 – 10 mm);
- **Rapidly increasing curing light intensities** to accommodate dentist demands for shorter polymerization times; and
- **Ultra-low cost curing lights** have experienced a dramatic increase in the availability to accommodate dentist demands for less costly devices. Some of these curing lights cost as little as 1% of a higher quality name-brand curing light.

These market forces have complicated the process of polymerization activation of tooth shade resin materials by increasing the complexities that need to be managed by dentists. The following is an illustrative list of challenges.

1. Factors related to the tooth colored resin materials:
    a) The tooth shade resin material instructions for use may cite a required minimum irradiance and curing time, but often these determining factors need to be inferred. Additionally, the minimum recommended irradiance for the tooth shade resin material commonly does not align with the output of the dentist's polymerization activator, and the curing times can conflict widely with those included in the directions for use of the polymerization activator.
    b) Incomplete polymerization occurs when insufficient light is delivered, and/or when the spectral properties of the polymerization activator do not align with the spectral requirements of the photoinitiator system incorporated into the tooth shade resin material. Not all polymerization activators can activate the photoinitiator systems included in the tooth shade resin material selected by the dentist, but commonly there is no information in either the material or curing light directions for use to notify the dentist of this fact. This is a concern given that the cytotoxicity of tooth shade resin materials increases when the photoinitiator systems in the material are incompletely polymerized.

c) Tooth shade dental material properties and performance testing occurs in laboratories and tends to occur on materials that are optimally polymerized with more than sufficient light delivery to meet the material manufacturer's minimum requirements. Conversely, clinical evidence from numerous countries consistently indicates that the curing lights used in clinical practice are often not in the condition necessary to deliver these optimal levels of light, resulting in incomplete clinical polymerization.

2. Factors related to the use of polymerization activators include:

a) Tooth shade resin material instructions for use may direct the dentist to use a curing light with a minimum intensity of 400 mW/cm^2 for 20 seconds. What is the dentist to do if his/her curing light produces seven times that intensity (e.g., 3,000 mW/cm^2)?

b) The instructions for use from some modern high-powered curing lights indicate that the device is intended for the polymerization of dental materials, and can be used for 1 second when the dentist is completing the layered build up of the material. No known tooth shade resin material can be polymerized with the energy that that specific curing light will deliver in one second, yet the dentist is using the device as directed.

c) Modern, powerful curing lights can increase tooth pulp temperatures at a rapid rate, and pulpal necrosis is associated with a temperature rise of only 5.5 degrees Celsius. Some dentists arbitrarily increase curing times in an effort to reduce the risk of incomplete polymerization. This can bring increased risks when using the most powerful curing lights capable of increasing surface temperatures by as much as 60 degrees Celsius in two seconds. Curing lights come with no information as to what are safe curing times or temperature increases. As a result, how is the dentist to safely adjust curing times to make up for differences in light output?

d) Some curing lights can experience rapid drops in available light delivery over clinically relevant distances (e.g., a 90% drop in irradiance from 0 mm to 10 mm). This rapid drop in available irradiance significantly affects the extent of polymerization and, as a consequence, the resulting material properties and performance.

e) New single peak LED curing lights do not deliver energy that has the spectral composition required to polymerize the photo initiators included in some tooth shade resin materials, yet there is no clear information that tells the dentist what type of curing light is required to safely polymerize all of the photo initiator systems included in a given tooth shade resin material. The presence of unreacted photoinitiators increases the cytotoxicity.

f) Some modern polymerization activators have highly inhomogeneous beam profiles, meaning that they have hot and cold spots across the light tip that can result in large differences (e.g., 10-fold) in energy delivery depending on the

positioning of the light tip relative to the tooth shade resin material being cured.

g) Studies of the condition and performance of polymerization activators used in private practice have consistently shown that a large portion are not well maintained, presenting with contamination, damage and/or output problems.

As previously stated, every tooth shade dental material has a specific energy requirement (i.e., an energy dosage) that must be met in order for that material to deliver the properties and performance intended by its manufacturer. This fundamental requirement contrasts with the current clinical reality whereby the actual energy delivered to a tooth shade resin material when it is being light cured intra-orally cannot currently be known or estimated by the dentist for the reasons cited above. It is further complicated by the fact that these materials cure from the top surface. This means that the top surface of the dental material is hard when tested with a dental explorer, even when only a small fraction of the required energy dose is delivered. Dentists have no way of knowing the depth of cure immediately below that top surface, yet that surface hardness can provide them with a false sense of security.

Experts will suggest that dentists can verify curing light output using a dental radiometer. However, dental radiometers cannot inform the dentist as to whether their curing light is functioning as expected and required because two decades of published research has demonstrated that dental radiometers are highly inaccurate and unreliable. Additionally, if the number provided were accurate, it represents irradiance at the curing light tip and provides no indication of the amount of light actually received by the tooth shade dental material being polymerized in the mouth at distances of up to 10 mm or more from that light tip.

Experts will suggest that dentists simply need to increase (e.g., double) curing times, but this off-label use of dental devices does not ensure that the particular brand or shade of tooth shade resin material will be completely polymerized because the:

- Energy dose requirement of the material can vary by as much as eight-fold;
- Performance of curing lights intra-orally can vary dramatically;
- Particular mode and curing time selected by the dentist can be insufficient;
- Directions for use on the material and the curing light can conflict;
- Curing light selected by the dentist may not be capable of activating the photoinitiator systems used in the selected tooth shade resin material; and
- Curing light may have degraded or not been maintained, so is not operating as expected or required.

Experts will suggest that the post curing of resin composite is sufficient to deliver the required properties and performance, regardless of the degree of cure achieved by the dentist when using their curing light. It is true that post curing occurs with light cured materials. However, post curing does not cause the degree of conversion increase from

50% to 80%, rather it can advance the degree of cure by up to an additional 10% on the base conversion (e.g., 50% will improve to 55%). Again, this post-curing effect differs by brand and shade.

Experts state that incomplete polymerization of resin composites is not the only issue that leads to premature restoration failure. They argue that ineffective moisture control is only one of many other issues lead to premature failure. This is correct. However, the particular properties and performance of a material will never be delivered to the patient if that tooth shade resin material is incompletely polymerized intra-orally. This fact is consistently confirmed by the chemists who formulate and evaluate tooth shade resin materials.

A great many experts also imply that light curing is easy. They do so by providing detailed procedural instructions to dentists for every stage of the restoration process, but then say *"...and then you light cure"* for the all-important step of polymerization upon which the delivery of material properties and performance depends.

Environmental impact

The environmental impact associated with the use of tooth shade resin materials or polymerization activators is unknown.

Economic impact

According to the National Institute of Dental and Craniofacial Research (NIDCR 2009-2013 Strategic Plan):

> *Even today, virtually everyone in the U.S. is at risk for tooth decay, which remains the single most common chronic child- hood disease—five times more common than asthma. Despite steady progress in learning how to better formulate and cure, or harden, dental composites in a damaged tooth, large composites shrink and stress the teeth to which they are bonded. Studies have shown that dental resin composites have an average replacement time of 5.7 years due to secondary decay and fracture of the restoration.*

Studies have shown that dental amalgam fillings last an average of 16 years, almost three times the average replacement rate of tooth shade resin material (dental composites). Studies have also shown that these two types of filling material can have comparable longevity.

American Dental Association data indicate that, in 2005, dentists used tooth shade resin material in 123 million fillings and amalgam in 52 million fillings. At an average cost of $200 per filling, these data suggest that there were something like $25 billion tooth share

resin fillings placed per year, with a replacement rate that is three times higher than is necessary.

When a restoration is replaced due to secondary decay or fracture, as identified by the NIDCR above, the subsequent restoration is invariably larger and ultimately can lead to an escalation in the intensity and cost of subsequent care.

Even if incomplete polymerization plays only a small role in causing the replacement rate of tooth shade resin material to be three times that of amalgam, a reduction in the incidence of incomplete polymerization will dramatically reduce the subsequent dental care costs of patients.

Dentists rely heavily on referrals to build their customer (patient) base. Patients are not happy when they experience post-operative sensitivity, or poor restoration performance that increases the cost and intensity of dental care. This patient dissatisfaction can cause the patient to limit their willingness to refer their dentist to others, and may cause them to consider switching dentists.

High quality manufacturers will benefit from complete intra-oral polymerization of their tooth shade resin materials because when problems related to post-operative sensitivity, rapid discoloration, increased wear, fracture, secondary decay and other factors are observed, dentists often switch dental material suppliers. They do so because they view the process of light curing as easy and do not consider that their curing light, curing time or curing technique could be resulting in incomplete polymerization. The material is blamed and the manufacturer of that material must then find a replacement customer.

Payers of dental care, patients, employers and governments, can experience rapid increases in costs due to incomplete polymerization. This is because a $200 restoration that should last 16 or more years is being replaced with increasingly larger restorations, ultimately resulting in a root canal, crown and possibly implant or denture.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Clarissa Clarke
[redacted]

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Clarke
[redacted]

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