Kerr
SYBRON DENTAL SPECIALTIES

August 25, 2006

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

Re: Citizen Petition Urging FDA to Take Regulatory Action to Safeguard the Public from Violative Dental Devices Distributed by Five Companies, Including Devices Manufactured in Unregistered Facilities and/or Subject to Tampering

Dear Sir or Madam:

The undersigned, on behalf of Kerr Corporation ("Kerr"), respectfully submits this Citizen Petition pursuant to 21 CFR § 10.30[1] to urge that the Food and Drug Administration ("FDA" or "Agency") initiate enforcement action to prevent the unauthorized sale and commercial distribution of violative prescription dental devices in the United States, including devices manufactured in unregistered facilities and/or subject to tampering.

I. Executive Summary

Kerr is a leading manufacturer of dental products and devices in the United States and throughout the world. Kerr has recently compiled documentation supporting the conclusion that five companies -- Chicago Dental Supply, Ethical Dental Supplies, International Dental Supply, Omni Dental Supply, and PA Dental Supplies -- are distributing violative prescription dental devices, used in invasive dental treatment, in violation of the Federal Food, Drug, and Cosmetic Act ("FFDCA" or "Act").[2] Supporting documentation is included in this Citizen Petition, including product invoices and photographs of the violative devices.

[1] 21 CFR § 10.30 (2006).

[2] 21 USC § 301 *et seq.* (2006).

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As an initial matter, many of the prescription dental devices commercially distributed by the five companies identified above originate from a Kerr manufacturing facility in Italy ("Scafati facility") that does not produce devices intended for commercial distribution in the United States, and therefore has not been registered with the FDA (or inspected by the FDA) as a device manufacturing facility.[3] Commercial distribution in the United States of medical devices not manufactured in an FDA-registered facility (and not "listed" with the FDA as being manufactured in such facility[4]) constitutes a clear violation of the FFDCA, and such devices are *per se* misbranded under Section 502(o) of the Act.[5]

The receipt and delivery of such misbranded devices is a prohibited act under Section 301(c) of the FFDCA.[6] If it were otherwise, and the FDA permitted the widespread sale of medical devices manufactured in unregistered and uninspected foreign facilities (and not "listed" with the FDA as being manufactured in such facility), the safety and integrity of medical devices commercially distributed in the United States would be greatly compromised. Patients could be exposed to many unknown risks since the Agency would have no way of ensuring the devices are manufactured according to good manufacturing practices ("GMPs") or quality system regulations ("QSRs"), or that they meet appropriate product specifications. Public health would also be jeopardized, particularly – as in the instant case – where medical devices are used in invasive dental treatment.

Most importantly, however, in addition to commercially distributing devices manufactured in an unregistered facility (and not "listed with the FDA as being manufactured in such facility), the five identified companies have also been distributing prescription dental devices that have been

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[3] Please note that the Scafati facility was once registered with FDA under different ownership. This registration was canceled in 1998. On July 28, 2006, registration and listing forms were submitted to the FDA in an effort to register the Scafati facility with the FDA. The devices identified in this Citizen Petition, however, were not "listed" in the Scafati registration and listing forms submitted to the Agency since these devices, when manufactured in the Scafati facility, are not intended for distribution in the United States.

[4] These devices are "listed" with the FDA for manufacture in FDA-registered facilities where the devices are intended for distribution in the United States.

[5] 21 USC § 352(o) (Section 502(o) of the FFDCA). Further, in many instances, the prescription dental devices commercially distributed in the United States had language indicating that the device was not packaged or intended for sale in the United States and Canada removed from product packages and labels.

[6] 21 USC § 331(c) (Section 301(c) of the FFDCA).

subject to tampering of product packaging and labeling - increasing the potential for device misuse, counterfeiting, and product adulteration.

This tampering activity has included one or a combination of the following:

- The removal of products from their original packaging;
- The removal of identifying lot numbers;
- The removal of package inserts containing vital safety information and directions for use; and
- The opening and resealing of product packaging.

Needless to say, these activities compromise device safety and patient health. Notably, the removal of devices from their packaging, as well as the opening and resealing of device packages, increase the likelihood that the devices may become adulterated or subject to counterfeiting. Moreover, it has come to our attention that devices removed from their original packaging have been repackaged in clear zip-lock bags without any package labeling, or distributed without any outer packaging or labeling at all. This repackaging activity, as well as the removal of package inserts containing directions for use and safety information, increases the probability the devices will be misused. To make matters worse, the removal of any identifying lot numbers compromises product safety and makes a product recall difficult if not impossible to conduct.

Medical devices that are commercially distributed in the United States in the absence of FDA-required labeling are considered misbranded under the FFDCA.[7] In fact, any alteration, destruction, or removal of medical device labeling that results in the product being adulterated or misbranded is a prohibited act under Section 301(k) of the FFDCA.[8] Moreover, persons engaged in the repackaging and relabeling activities described above are required to register their facilities with the FDA, and comply with a host of additional medical device regulations.[9] We question whether the unknown entities who have engaged in these tampering activities are registered with the FDA, causing the devices themselves to be *per se* misbranded under Section 502(o) of the

[7] 21 USC § 352(f) (Section 502(f) of the FFDCA).

[8] 21 USC § 331(k) (Section 301(k) of the FFDCA).

[9] 21 CFR § 807.20.

Act.[10] As noted above, the receipt and delivery of such misbranded devices is also a prohibited act under Section 301(c) the FFDCA.[11]

The regulatory violations discussed above have been documented in this Citizen Petition for the following dental devices: OptiBond® Solo Plus™; Herculite XRV™ (four different versions); and Temp Bond®.[12] Although each regulatory violation standing alone is worthy of FDA enforcement, a large number of misbranded devices had multiple violations. For example, many misbranded devices were both manufactured in an unregistered facility and subject to extensive tampering. It should be emphasized that when these devices are manufactured in an FDA-registered facility, are packaged and labeled appropriately, and distributors lawfully distribute these devices in their intended markets, these devices are entirely lawful and are neither adulterated nor misbranded. When, however, the devices are manufactured in unregistered facilities, with modified packaging and labeling, the commercial distribution of such devices in the United States by the five companies identified above is clearly in violation of FDA regulatory requirements. Accordingly, we respectfully request that the FDA initiate enforcement action – including but not limited to pursuit of an injunction against the five identified companies – to prohibit the commercial distribution of violative medical devices intended for use in invasive dental treatments.

II. Action Requested

We petition the FDA to take immediate action to cease the unlawful distribution of violative dental devices. Such action may include, but is not limited to: (1) issuance of Warning Letters to the five companies distributing such devices in the United States; and/or (2) initiation of an injunctive action against each of the five companies distributing such devices in the United States.

III. Statement of Grounds

Medical devices are stringently regulated by the FDA, and are subject to a wide array of statutory and regulatory requirements to ensure their safety and efficacy. The failure to comply with these statutory and regulatory requirements results in the adulteration and/or misbranding of medical

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[10] 21 USC § 352(o) (Section 502(o) of the FFDCA).

[11] 21 USC § 331(c) (Section 301(c) of the FFDCA).

[12] The four different versions of Herculite XRV™ include Herculite XRV™ Unidose Enamel A1, Unidose Enamel A2, Syringe Enamel A2, and Syringe Enamel A3.

devices. Further, the receipt and delivery of adulterated or misbranded medical devices constitutes a prohibited act under Section 301(c) of the FFDCA. In the instant case, we have compiled documentation supporting the conclusion that Chicago Dental Supply, Ethical Dental Supplies, International Dental Supply, Omni Dental Supply, and PA Dental Supplies are distributing misbranded prescription dental devices in interstate commerce in violation of the FFDCA.

Many of these devices originate from an unregistered facility (and have not been "listed" with the FDA as being manufactured in such facility) and/or have been subject to package and label tampering. Provided below is an overview of FDA medical device regulation, a description of the dental devices addressed in this Citizen Petition, a description of the nature and type of tampering activity, and extensive documentation (including photographs and invoices) of 67 instances in which misbranded devices were purchased from the companies identified above.

A. Background

1. FDA Regulation of Medical Devices

FDA's Center for Devices and Radiological Health ("CDRH") is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. A medical device is defined in Section 201(h) of the FFDCA as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- "recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them";
- "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals"; or
- "intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."[13]

[13] 21 USC § 321(h) (Section 201(h) of the FFDCA).

If a product is labeled, promoted, or used in a manner that meets the preceding definition, it is regulated by the FDA as a medical device and subject to a variety of pre-marketing and post-marketing regulatory controls. For example, some devices require a pre-market clearance and submission of a 510(k) to FDA, while others may require pre-market approval ("PMA").[14] Regardless of whether marketing clearance or approval is required, medical device manufacturers must comply with FDA "general controls," including but not limited to: facility registration; medical device listing; marketing surveillance requirements; quality control requirements and GMPs; and general labeling requirements.[15] Notably, every person who owns or operates any establishment "in any State engaged in the manufacture, preparation, propagation, compounding, or processing" of a device must (among other things) register his or her name, place of business, and all such establishments with the FDA.[16] Similarly, any establishment within a foreign country engaged in these activities with respect to a device that is imported or offered for import in the United States must be registered with FDA and list its devices.[17]

The term "manufacture, preparation, propagation, compounding, or processing" is defined broadly to include repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.[18] Accordingly, if any finished devices are relabeled or repackaged, then the establishment performing these activities must be registered with the FDA and list these devices.

Not only is it unlawful to repackage and relabel medical devices without complying with the required establishment registration and medical device listing requirements, but - as explained below - the failure to comply with these requirements results in the devices being misbranded and/or adulterated under the FFDCA.

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[14] 21 CFR § 807.81; 21 CFR Part 814. Please note that in many instances no pre-market clearance or approval is needed.

[15] 21 CFR Parts 801, 803, 806, 807, 820, 821, 822.

[16] 21 USC § 360(b), (c) (Section 510(b), (c) of the FFDCA).

[17] 21 USC § 360(i), (j) (Section 510(i), (j) of the FFDCA).

[18] 21 USC § 360(a)(1) (Section 510(a)(1) of the FFDCA).

2. Device Adulteration and/or Misbranding.

Medical devices that do not meet FDA regulatory requirements are adulterated and/or misbranded under the FFDCA. A device is considered adulterated if, among other things, "the methods used in, or the facilities and controls used for, its manufacture, packing, storage, or installation are not in conformity" with applicable GMP or QSR requirements.[19] Meanwhile, a medical device is deemed to be misbranded (in pertinent part) if:

- Its labeling is false or misleading in any particular.[20]
- Any word, statement, or other information required by or under authority of the FFDCA to appear on the label or labeling is not "prominently placed thereon."[21]
- It was manufactured, prepared, propagated, compounded, or processed in an establishment that is not registered with the FDA.[22]

Section 301(c) of the FFDCA also prohibits the receipt and delivery of any adulterated or misbranded medical device in interstate commerce.[23] Moreover, Section 301(k) of the FFDCA prohibits the "alteration, mutilation, destruction, or removal of the whole or any part" of any medical device labeling (while it is held for sale after shipment in interstate commerce) that results in the device being adulterated or misbranded.[24]

The requirements and limitations set forth by the FFDCA are intended to ensure the safety and effectiveness of finished medical devices. Unfortunately, as discussed in greater detail below, five distributors are distributing prescription dental devices that fail to comply with FDA regulatory requirements.

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[19] 21 USC § 351(h) (Section 501(h) of the FFDCA).

[20] 21 USC § 352(a) (Section 502(a) of the FFDCA).

[21] 21 USC § 352(c) (Section 502(c) of the FFDCA).

[22] 21 USC § 352(o) (Section 502(o) of the FFDCA).

[23] 21 USC § 331(c) (Section 301(c) of the FFDCA).

[24] 21 USC § 331(k) (Section 301(k) of the FFDCA).

B. FDA Regulation of the Lawful Prescription Dental Devices Distributed by Kerr

The prescription dental devices being distributed by the five companies identified in this Citizen Petition are:

- OptiBond® Solo Plus™ Bottle Refill – Domestic Part # 31513; International Part # 29692
- Herculite XRV™ Unidose Enamel A1 - Domestic Part # 29835; International Part # 23036
- Herculite XRV™ Unidose Enamel A2 - Domestic Part # 29836; International Part # 23037
- Herculite XRV™ Syringe Enamel A2 - Domestic Part # 29798; International Part # 22860
- Herculite XRV™ Syringe Enamel A3 - Domestic Part # 29799; International Part # 22861
- Temp Bond® - Domestic Part # 00370; International Part # 61087 or 61086

OptiBond® Solo Plus™ is a resin tooth bonding agent designed to be used in direct situations (i.e., composite to enamel and/or dentin, composite repair, porcelain repair, composite to metal, amalgam sealing, bonding composite core build-up materials) and indirect situations (i.e., veneers, inlays, crowns). It is a Class II prescription medical device with 510(k) pre-market clearance.[25]

Herculite XRV™ Unidose Enamel A1, Unidose Enamel A2, Syringe Enamel A2, and Syringe Enamel A3 are dental composite restorative materials designed to permit the duplication of natural tooth color. The Herculite XRV products are Class II prescription medical devices with 510(k) pre-market clearance.[26]

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[25] OptiBond® Solo Plus 2™, K991808 (July 9, 1999). The 510(k) application contained samples of product labeling and directions for use.

[26] Herculite XRV™, K943642 (November 17, 1994). The 510(k) application contained samples of its labeling and directions for use.

Temp Bond® is a temporary cement for trial cementing restorations or cementing temporary crowns and bridges. Temp Bond is a Class I medical device not requiring 510(k) pre-market clearance.

These devices, when lawfully marketed in the United States, are manufactured in one of two FDA-registered U.S. facilities ("Romulus facility" and "DMC facility").[27] Some of these U.S. products are also subsequently packaged or repackaged at an FDA registered facility in Mexico. Although the vast majority of the devices manufactured in the these facilities are meant for sale in the United States and labeled with domestic part numbers, some of these devices are also intended for sale in foreign markets and labeled with international part numbers. These domestic and international part numbers are placed on product packages to identify their intended markets, and may (along with lot numbers) be used for recall purposes.

All of these dental devices, when lawfully distributed in the United States, are labeled and packaged in compliance with FDA regulatory requirements. Among other things, the devices all contain: (1) product packages with appropriate labeling; (2) identifying lot numbers; (3) domestic or international part numbers; (4) manufacturing location; and (5) package inserts containing directions for use, intended use, and safety information. In fact, the appropriate product labeling and package inserts for the OptiBond® Solo Plus™ and Herculite XRV™ products were cleared by the FDA via the 510(k) process.

As previously explained, when these Kerr devices are manufactured in an FDA-registered facility, are packaged and labeled appropriately, and distributors distribute these devices in their intended markets, these devices are entirely lawful and are neither adulterated nor misbranded. When, however, the devices are manufactured in unregistered facilities, with modified packaging and labeling, the commercial distribution of such devices in the United States by the five companies identified herein is clearly in violation of FDA regulatory requirements.

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[27] The Romulus facility is located at 28200 Wick Road, Romulus, MI 48174-2600. The DMC facility is located at 1717 West Collins, Orange, CA 92867. These devices are also "listed" with the FDA for distribution in the United States from these registered facilities.

C. Documentation That Misbranded Prescription Dental Devices Were Distributed by Chicago Dental Supply, Ethical Dental Supplies, International Dental Supply, Omni Dental Supply, and PA Dental Supplies

1. Summary of Violations

Kerr has recently compiled documentation supporting the conclusion that five companies - Chicago Dental Supply, Ethical Dental Supplies, International Dental Supply, Omni Dental Supply, and PA Dental Supplies - are distributing misbranded prescription dental devices used in invasive dental treatment. A wide range of regulatory violations have been identified.

- These companies are distributing a number of OptiBond® Solo Plus™, Herculite XRV™, and Temp Bond® products that were manufactured in a facility located in Scafati, Italy. This facility is not registered with the FDA as a manufacturer or exporter of medical devices, and the products made at this facility are not "listed" with the FDA as being manufactured in such facility since they were never intended for the United States market. As noted above, dental devices originating from an unregistered manufacturing facility are misbranded under the FFDCA, and may not be offered for sale in the United States.

- Package inserts (containing directions for use, indications for use, and product warnings) were removed from a number of dental device packages.[28] The removal of these FDA-

[28] The package insert for Temp Bond® not only provides directions for use, but cautions that "Temp-Bond contains eugenol. A small number of patients may experience an allergic reaction to eugenol. Caution is recommended with these patients." Similarly, the package inserts for Herculite HRV™ products not only provide extensive directions for use but also caution that the product: (1) "Contains phosphoric acid. Avoid contact with skin, eyes, and soft tissue. In case of contact with skin or eyes, flush immediately with water, get medical attention for eyes. Do not take internally."; (2) "Uncured resin materials may cause contact dermatitis. Avoid prolonged exposure of uncured resins to skin and soft tissue."; and (3) "Uncured methacrylate can damage the pulp." Meanwhile, the package insert for OptiBond® Solo Plus™ contains extensive directions and indications for use, along with the following three cautionary statements: (1) "Contains phosphoric Acid. Avoid contact with skin, eyes, and soft tissue. In case of contact with skin or eyes, flush immediately with water, get medical attention for eyes. Do not take internally."; (2) "Contains hydrofluoric acid (HF). Avoid contact with skin, eyes, and soft tissue. In case of contact with skin or eyes, flush immediately with water. Get medical attention. Do not take internally. The use of a rubber dam is recommended for safety when using HF. Wash thoroughly (ALL GEL MUST BE REMOVED) and air dry."; and (3) "Uncured methacrylate resin may cause contact dermatitis and damage the pulp. Avoid contact with skin, eyes, or soft tissue. Wash thoroughly with water after contact."

cleared package inserts greatly increases the chance of product misuse and patient harm, and exposes dental hygienists, dentists, and patients to potential safety risks. For example, the OptiBond® Solo Plus™ and Herculite XRV™ product inserts caution that the products contain methacrylate (a substance which can cause contact dermatitis) and that contact with skin, eyes, or soft tissue should be avoided. Similarly, the Temp Bond® package insert cautions that the product contains eugenol, a substance that causes an allergic reaction in some patients. When a dentist is put on notice that a product contains eugenol, and knows that a particular patient will experience an allergic reaction, the dentist may avoid patient harm by choosing to substitute a non-eugenol formulation known as Temp Bond® NE. Information contained in package inserts is clearly important to the practice of dentistry and patient health. Moreover, a device lacking in such information would be in violation of 21 CFR § 801.109, which requires the labeling of prescription devices to bear (among other things) information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contradictions, side effects, and precautions under which the device can be safely used.[29] Such a device would be misbranded and may not be offered for sale in the United States.[30] Package inserts are also often important to employee safety and compliance with the Occupational Safety and Health Administration's ("OSHA") right-to-know requirements.

- Identifying lot numbers were removed from the labels of a number of dental products. By way of background, all Kerr dental devices have lot numbers which provide traceability to all production records, serve to identify the device's manufacturing location, and are used to track devices in the event of a product recall.[31] The removal of this lot number makes product tracking and effectuation of appropriate recalls difficult if not impossible.

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[29] 21 CFR § 801.109.

[30] A medical device is misbranded if "any word, statement, or other information required by or under authority of [the FFDCA] to appear on the label or labeling is not prominently placed thereon with such conspicuousness." 21 USC § 352(c) (Section 502(c) of the FFDCA).

[31] Please note that even when the lot number is removed, we can often determine where the product has been produced because Temp Bond® is produced only in Kerr's Romulus and Scafati facilities, while adhesives and composites are produced only in Kerr's DMC and Scafati facilities.

- A large number of devices were removed from their original FDA-cleared packaging. These devices were then repackaged in clear zip-lock bags or distributed without any packaging at all, increasing the potential for consumer confusion, counterfeiting, and product adulteration.

- A number of device packages were opened and resealed, presumably to alter information on the product label.[32] In the instant case, when plastic bags with a heat seal were trimmed to a smaller size and the seal moved from the standard location, it was self-evident the device package had been tampered with. This activity increases the potential for counterfeiting and product adulteration.

Although each of these regulatory violations standing alone would be worthy of FDA enforcement, a large number of devices identified in this Citizen Petition had multiple violations. If the persons engaged in the relabeling and repackaging activities described above are not registered with the FDA, the devices would be misbranded and may not be offered for sale in the United States. As noted above, medical devices without FDA-required labeling are also considered misbranded under the FFDCA.[33] In fact, any alteration, destruction, or removal of medical device labeling that results in the product being adulterated or misbranded is a prohibited act under Section 301(k) of the FFDCA.[34] Moreover, these devices would be adulterated if the methods used in, and facilities and controls used for the repackaging, relabeling, and storage of the devices do not conform to quality systems regulations, as prescribed in 21 CFR Part 820. FDA has issued Warning Letters to repackagers and relabelers of medical devices for violations of this kind.[35]

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[32] In many instances, the prescription dental devices commercially distributed in the United States had language indicating that the device was not packaged or intended for sale in the United States and Canada removed from product packages and labels.

[33] 21 USC § 352(f) (Section 502(f) of the FFDCA).

[34] 21 USC § 331(k) (Section 301(k) of the FFDCA).

[35] For example, in a 8/13/93 *Warning Letter to Pitt Enterprises (Silicone) Ltd.*, the FDA noted that "As a repacker and relabeler of medical devices, your firm is required to register with FDA on an annual basis. Your failure to register causes the devices to be misbranded under Section 502(o) of the Act. The repacking, relabeling, and distribution of adulterated and misbranded medical devices is prohibited under Section 310(a) and 301(k) of the Act." In this same letter, FDA also noted that the "devices repacked, relabeled and distributed by your firm are adulterated within the meaning of Section 510(h) of the Act, since the methods used in, and the facilities used and controls used for, the repacking, relabeling, and storage of the devices do not conform to good manufacturing practices, as prescribed in Title 21, Code of Federal Regulations (CFR), Part 820."

We emphasize that we have no documentation indicating which entities have tampered with the above-mentioned devices. All we know at this point in time is that the five distributors identified in this Citizen Petition have been commercially distributing in the United States misbranded medical devices.

2. Evidence Confirming Device Misbranding

We have compiled extensive documentation that 67 misbranded OptiBond® Solo Plus™, Herculite XRV™, and Temp Bond® devices were purchased from five distributors including Chicago Dental Supply, Ethical Dental Supplies, International Dental Supply, Omni Dental Supply, and PA Dental Supplies. This documentation, which includes a descriptive list of all misbranded devices purchased from each company, multiple photographs of each misbranded device, as well as invoices and shipping labels, are provided in Attachments A through G to this Citizen Petition.

Attachment A provides a road-map for all of the documentary evidence included in this Citizen Petition. Attachment A is an evidentiary table entitled "List of Misbranded Dental Devices," that contains extensive information on each of the 67 misbranded devices. Photographic evidence documenting the condition of the devices upon receipt from the named distributors support all information contained in the table, which sets forth the following:

- The first column provides a convenient numbering system for reference to each misbranded device described in this Citizen Petition (and which correlates with the tabs contained in the Attachments).[36]

- The second column provides the name of the entity distributing the device.

- The third column identifies the date on which the device was purchased ("Invoice Date"). All misbranded devices were purchased via the Internet on a number of occasions over the past year. These devices were subsequently shipped to a dentist's office in California.

[36] Photographs of each device are separated by numbered tabs in the Attachments. These tabs correlate with numbers on the evidentiary table. For example, photographs of the device described in row "1" can be found in tab "1," photographs of the device described in row "2" can be found in tab "2," etc.

- The fourth column identifies the type of device. For example, OptiBond® Solo Plus™ Bottle Refill, Herculite XRV™ Unidose Enamel A1, Herculite XRV™ Unidose Enamel A2, Herculite XRV™ Syringe Enamel A2, Herculite XRV™ Syringe Enamel A3, or Temp Bond® Regular.

- The fifth column identifies the lot number of the misbranded device. In some instances, the lot number is listed as "Unknown" because it was removed by a third party without authorization from Kerr.

- The sixth column identifies the device manufacturing location. "Scafati (unregistered)" signifies that the device was manufactured in an unregistered facility in Scafati, Italy. This also means that the device has not been "listed" with the FDA as being manufactured in such facility. "DMC (registered)" signifies that the device was manufactured in a registered US facility located in Orange, CA.

- The seventh column identifies devices that had their package inserts removed. An "X" in this column signifies the package insert was removed.

- The eighth column identifies devices that were removed from their original packaging. An "X" in this column signifies the device was removed from its original packaging. Lawful OptiBond® Solo Plus™ Bottle Refills and Herculite XRV™ dental devices distributed by Kerr are packaged in FDA-approved heat-sealed packaging with appropriate labeling. Devices that were removed from their original lawful packaging were either repackaged in clear zip-lock bags or distributed without any packaging at all.

- The ninth column identifies devices that had their packaging opened and resealed. An "X" in this column signifies the device package was opened and resealed. Packages which are known to be opened and resealed are plastic bags with a heat seal. When the bag has been trimmed to a smaller size and the seal moved from the standard location, it is evident that the package has been tampered with.

- The tenth column identifies devices that had language indicating the device was not packaged or intended for sale in the United States or Canada removed from the device outer package. An "X" in this column signifies such language was removed from the device package.

- The eleventh column identifies devices that had the statement "Not for Sale in the US or Canada" removed from the device label. An "X" in this column signifies this statement was removed from the device label.

- The twelfth column identifies devices that had their lot numbers removed. An "X" in this column signifies the device had its lot number removed.

- The thirteenth column identifies where photographs of the misbranded device can be found in the Attachments by providing Bates numbers. All Attachments, including the evidentiary table, photographs, and invoices are Bates-stamped for easy reference.

Attachments B, C, D, E, and F contain labeled photographic images of the misbranded devices listed in the evidentiary table. More specifically, Attachment B (Tabs 1-21) contains photographs of devices purchased from Chicago Dental Supply, Attachment C (Tabs 22-32) contains photographs of devices purchased from Ethical Dental Supplies, Attachment D (Tabs 33-43) contains photographs of devices purchased from International Dental Supply, Attachment E (Tabs 44-61) contains photographs of devices purchased from Omni Dental Supply, and Attachment F (Tabs 62-67) contains photographs of devices purchased from PA Dental Supplies. These Attachments generally contain photographs of the front and back of each device. Additional photographs from other angles are provided as needed to document violations. Kerr certifies that the photographs reflect the condition of the devices as received.

Finally, Attachment G contains product invoices for these devices, as well as shipping labels documenting that these misbranded devices were shipped by the five identified companies to a dentist in the United States. Provided in Attachment G are: 4 invoices and shipping labels from Chicago Dental Supply reflecting the purchase of 21 misbranded dental devices from the company; 4 invoices and shipping labels from Ethical Dental Supplies reflecting the purchase of 11 misbranded devices from the company; 3 invoices and shipping labels from International Dental Supply reflecting the purchase of 11 misbranded devices from the company; 5 invoices and shipping labels from Omni Dental Supply reflecting the purchase of 18 misbranded devices from the company; and 2 invoices and shipping labels from PA Dental Supplies reflecting the purchase of 6 misbranded devices from the company.

Please note that although we have compiled evidence of 67 violations, we have no reason to believe the identified companies limited the distribution of these devices to those documented in this Citizen Petition. The sale of these misbranded devices may indeed be a widespread practice.

Provided below is a synopsis of the purchases.

a. Chicago Dental Supply

Chicago Dental Supply is an online retailer and distributor of dental devices located at 8119 Zionsville Rd, Indianapolis, IN 46268.[37] 21 misbranded dental devices were purchased from the company on November 3, 2005, December 8, 2005, January 12, 2006, and February 23, 2006. The following regulatory violations were identified:

- 17 devices were manufactured in an unregistered overseas facility (Scafati) and may not be offered for sale or distributed in the United States.
- 2 devices had their package inserts containing important safety information and directions for use removed.
- 14 devices were removed from their original packaging and repackaged in plastic zip-lock bags.
- 6 devices had language indicating the device was not packaged or intended for sale in the U.S. removed from their product packages.
- 9 devices had language indicating the device was not for sale in the U.S. removed from their product labels.
- 1 device had its lot number removed.

Photographs of these misbranded devices are found in Attachment B (Tabs 1-21). Product invoices and shipping labels are found in Attachment G (Chicago Dental Supply).

b. Ethical Dental Supplies

Ethical Dental Supplies is an online retailer and distributor of dental devices located at 3563B Lawson Blvd., Oceanside, NY 11572.[38] 11 misbranded dental devices were purchased from the

[37] Chicago Dental Supply is also known as Best Buy Dental Supply. The company's website can be found at http://www.bestbuydentalsupply.com/shop/buyprod/index.asp.

[38] Ethical Dental Supplies' website can be found at http://www.ethicaldental.com/

company on July 12, 2005, August 15, 2005, September 19, 2005, and December 8, 2005. The following regulatory violations were identified:

- 9 devices were manufactured in an unregistered overseas facility (Scafati) and may not be offered for sale or distributed in the United States.
- 2 devices had their package inserts containing important safety information and directions for use removed.
- 2 devices were removed from their original packaging and distributed without any outer packaging.
- 7 devices had language indicating the device was not packaged or intended for sale in the U.S. removed from their product packages.
- 2 devices had their lot numbers removed.

Photographs of these misbranded devices are found in Attachment C (Tabs 22-32). Product invoices and shipping labels are found in Attachment G (Ethical Dental Supplies).

c. International Dental Supply

International Dental Supply is an online retailer and distributor of dental devices located at 8205 West 20th Avenue, Hialeah, FL 33014.[39] 11 misbranded dental devices were purchased from the company on August 12, 2005, November 3, 2005, and December 8, 2005. The following regulatory violations were identified:

- 8 devices were manufactured in an unregistered overseas facility (Scafati) and may not be offered for sale or distributed in the United States.
- 1 device was removed from its original packaging and repackaged in a plastic zip-lock bag.

[39] International Dental Supply's website can be found at http://idsdental.stores.yahoo.net/info.html/

- 3 devices had language indicating the device was not packaged or intended for sale in the U.S. removed from their product packages.

- 1 device had language indicating the device was not for sale in the U.S. removed from the product label.

- 2 devices had their lot numbers removed.

Photographs of these misbranded devices are found in Attachment D (Tabs 33-43). Product invoices and shipping labels are found in Attachment G (International Dental Supply).

d. Omni Dental Supply

Omni Dental Supply is an online retailer and distributor of dental devices located at 1412 Ave M # 2321, Brooklyn, NY 11230.[40] 18 misbranded dental devices were purchased from the company on July 11, 2005, September 16, 2005, November 3, 2005, January 12, 2006, and February 23, 2006. The following regulatory violations were identified:

- 12 devices were manufactured in an unregistered overseas facility (Scafati) and may not be offered for sale or distributed in the United States.

- 10 device packages were opened and resealed.

- 12 devices had language indicating the device was not packaged or intended for sale in the U.S. removed from their product packages.

- 10 devices had language indicating the device was not for sale in the U.S. removed from their product labels.

- 1 device had its lot number removed.

Photographs of these misbranded devices are found in Attachment E (Tabs 44-61). Product invoices and shipping labels are found in Attachment G (Omni Dental Supply).

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[40] Omni Dental Supply's website can be found at http://www.omnidentalsupply.com/

e. PA Dental Supplies

PA Dental Supplies is an online retailer and distributor of dental devices located at 644 Shrewbury Commons Avenue, Unit 256, Shrewbury PA 17361.[41] 6 misbranded dental devices were purchased from the company on November 4, 2005, and January 12, 2006. The following regulatory violation was identified:

- 6 devices were manufactured in an unregistered overseas facility (Scafati) and may not be offered for sale or distributed in the United States.

Photographs of these misbranded devices are found in Attachment F (Tabs 62-67). Product invoices and shipping labels are found in Attachment G (PA Dental Supplies).

IV. Conclusion

For the reasons listed herein, FDA should immediately initiate enforcement action, including but not limited to, the pursuit of an injunction against the five identified companies to prohibit the further commercial distribution of violative medical devices intended for use in invasive dental treatment.

V. Environmental Impact

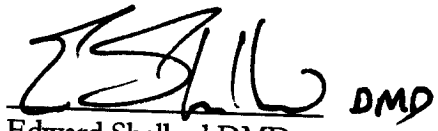
Nothing requested in this petition will have an impact on the environment, and thus, this petition should be categorically excluded from any applicable requirements in 21 CFR pt. 25, subpt C and 21 CFR § 25.40.

[41] Information on PA Dental Supplies may be found at http://www.net32.com/advertising/net32-vendors/spotlights/pa-dental-vs.php

VI. 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.

Very truly yours,



Edward Shellard DMD
President
Kerr Corporation
1717 West Collins Avenue
Orange, CA 92867
(714) 516-7400

Jaffe, Lyle D

From: Sadler, Frederick
Sent: Tuesday, September 05, 2006 2:01 PM
To: 'Rubin, Paul'
Cc: Jaffe, Lyle D; Butler, Jennie C; Dorsey, Betty B; Lazaroff, Joy B. (CDRH)
Subject: RE: Kerr/Sybron Citizen Petition

Sensitivity: Confidential

Good afternoon, Paul, and many thanks for your confirmation. By copy of this email, I am confirming that Dockets Management will log and make publicly available the Kerr Citizen Petition, exactly as it was submitted. We very much appreciate your help in confirming your client's intention to have the copy released in its entirety. If you have any questions on releasability or the Freedom of Information Act, please don't hesitate to call me. If you have questions on the processing in Dockets Management, Lyle Jaffe or Jennie Butler are always available to speak with you.

Best wishes,

Fred

Fred Sadler, HFI-30 (room 6-30)
Div. of Freedom of Information, OMP
Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 827-6548 (direct)
(301) 827-6567 (main)
(301) 443-2896 (fax)

-----Original Message-----
From: Rubin, Paul [mailto:PRubin@PattonBoggs.com]
Sent: Tuesday, September 05, 2006 1:55 PM
To: Sadler, Frederick
Subject: Kerr/Sybron Citizen Petition
Importance: High
Sensitivity: Confidential

Fred -

Thank you, once again, for discussing your concerns about the Citizen Petition with me. I just spoke with my client (Kerr/Sybron), and they authorize the FDA to file the Citizen Petition as is - including all attachments. My client understands that these attachments will be publicly available.

It would be greatly appreciated if you could confirm receipt of this email, and confirm that the agency expects to officially file the petition today. Please let me know if you have any additional questions or concerns. Thank you.

Very truly yours,

Paul Rubin

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