



**A SAFER DENTAL VISIT**

# The significance of the US Food and Drug Administration for dental professionals and safe patient care

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The US Food and Drug Administration (FDA) is a federal government agency responsible for protecting the health of the public through oversight and regulation of certain classes of products (Box 1).<sup>1</sup> The FDA operates 7 different centers within it, each responsible for products that fall under its jurisdiction (Box 2).<sup>2</sup> However, since the time when the FDA was created, products have been introduced that may have multiple mechanisms of action. A complex device may contain both a drug and a biologic, a device and a drug, or other combinations of drug, biologic, and device. In such situations, a determination of the product’s primary mechanism of action is made by the FDA’s Office of Combination Products, and the designation of the relevant center to handle the product is based on this determination.<sup>3</sup> For example, an implant that releases antibiotics could be a device whose purpose is to deliver a drug (the main mechanism of action), or a bone cement could release a drug whereas its primary mechanism of action is as a cement. For dental professionals, the most relevant FDA centers are those that regulate drugs, medical devices, and biologics.

**THE US FOOD AND DRUG ADMINISTRATION AND DENTAL PROFESSIONALS**

The FDA does not regulate dentists or determine which products a

**BOX 1**

**Key message (purpose of the US Food and Drug Administration).**

The US Food and Drug Administration is responsible for protecting the health of the public through oversight and regulation of certain classes of products that include many dental products.

**BOX 2**

**The 7 Centers of the US Food and Drug Administration.**

- Center for Drug Evaluation and Research\*
- Center for Devices and Radiological Health\*
- Center for Biologics Evaluation and Research\*
- Center for Tobacco Products
- Center for Veterinary Medicine
- Center for Food Safety and Applied Nutrition
- National Center for Toxicological Research

\* Most relevant to dental professionals.

dentist may use; it regulates industry and products falling under its jurisdiction. Most items used in the dental operatory are regulated as a drug or as a medical device, and biologics and devices emitting radiation (for example, lasers) are also incorporated into dental procedures. Lasers fall under the jurisdiction of the Center for Devices and Radiological Health, and drugs such as local anesthetics and antibiotics fall under the jurisdiction of the Center for Drug Evaluation and Research.

Medical devices encompass a wide range of dental products, from simple explorers and mirrors to handpieces, restorative materials, dental implants, instrument washers and washer-disinfectors, and high-level disinfectants and sterilants. A bone-graft material used in dentistry for sinus augmentation and treatment of localized alveolar ridge defects is 1 example of a dental combination product and contains recombinant human bone morphogenetic protein-2 (the biologic) delivered on an absorbable collagen sponge (the device).

The FDA reviews product submissions to determine what is safe and what kinds of data have been submitted to support a product, to substantiate the intended product claims, and to prove that a product will not harm patients. In doing so, the FDA acts in the best interest of patients. Since the FDA clears and approves dental products demonstrating safety and efficacy, it also is acting in the best interest of dental professionals using them.

**US FOOD AND DRUG ADMINISTRATION –CLEARED AND –APPROVED DENTAL PRODUCTS**

The processes, requirements, and time from submission to completion differ for drugs and various types of devices. Drugs generally require a longer FDA approval process. Devices are classified into classes I, II, and III (Box 3) on the basis of the level of risk associated with use of the device. Class I devices—for

## BOX 3

### Examples of devices used in dentistry.

Mouth Mirror (Class I)

Handpiece (Class I)

Surgical Mask (Class II)

National Institute for Occupation Safety and Health respirator (Class II)

Pit-and-fissure Sealant (Class II)

Total Temporomandibular Joint Prosthesis (Class III)

example, a mouth mirror—have the lowest level of risk and are therefore mostly exempt from requirements for applications to the FDA. Most dental devices are Class II devices and require a 510(k) submission, which must show that the device is at least as safe and effective as a substantially equivalent device (the “predicate device”) that is already legally marketed and is not subject to premarket approval (see below). The FDA reviews the information provided and may also request more information. If the 510(k) submission is successful, the FDA issues a letter stating that it found the product to be substantially equivalent to a predicate device and that the company can market the product.

Class III devices (those with the highest level of risk) require premarket approval, which is more stringent and takes longer. The company must submit sufficient valid scientific evidence such that the FDA can ensure that the device is safe and effective for its intended use. The process typically requires clinical data and a presentation to an advisory panel before a decision being made by the FDA on whether to grant approval to the manufacturer to market the product. On occasion, devices may be reclassified by the FDA, as happened in 2013 when blade-form implants were reclassified from a Class III to a Class II device on the basis of data supporting their safety, long-term success, and survivability.<sup>4</sup>

Regardless of how a product is classified or the type of submission required, on a broader level the basic objective of the FDA review process is to ensure that products brought to market are safe and effective for the public and demonstrate efficacy for the proposed claims. As dental professionals, it is also reassuring to know that the FDA reviews products on the basis of the level of risk and that devices that are cleared or approved by the FDA have been found to be effective and safe for use.

#### THE DENTAL INDUSTRY, DENTAL PRODUCT LABELING, AND THE US FOOD AND DRUG ADMINISTRATION

The FDA does not approve manufacturers but regulates products. In addition to submitting data supportive of a product’s safety and efficacy, the manufacturer must submit drafts of the packaging and proposed instructions for use. The FDA reviews these and can request changes. Such reviews help dental professionals by helping ensure that the instructions for use are clear and appropriate. After product clearance or approval, the manufacturer must comply with FDA requirements such as maintaining Good Manufacturing Practices (GMPs) in its facilities and reporting adverse events. GMPs are applicable whether the product is manufactured in the United States or overseas. The FDA inspects manufacturing facilities to verify that they comply with GMPs and can arrange an appointment for an inspection or turn up unannounced. Warning letters are issued if there are violations in GMPs or in product claims or marketing. If a company makes substantial changes to its products or claims, it must submit a new application to the FDA. In addition, manufacturers may not promote the off-label use of their products. In extreme situations, violations could result in the company’s having to discontinue marketing the

product or close down production either temporarily or permanently and pay fines.

#### OFF-LABEL USE OF PRODUCTS—WHAT IT MEANS FOR DENTAL PROFESSIONALS

Off-label use refers to the use of a product for a purpose other than that for which it is approved or cleared by the FDA. This does not mean that an off-label use is necessarily clinically contraindicated, and the FDA does not have jurisdiction to prevent a dental or medical professional from using a product off label.<sup>5</sup> However, if you decide to use a product off label, this decision should only be taken if there is ample scientific evidence supporting the efficacy and safety of that product. For example, a high-level disinfectant and sterilant is intended for use for semicritical, heat-sensitive instruments (except handpieces)<sup>6</sup>; its use as a disinfectant for environmental surfaces would not only be off label, it could not be justified because there is no basis for using it in this manner. Conversely, use of some products off label could be justified, including using 5% sodium fluoride varnish, which is cleared as a medical device to treat dentinal hypersensitivity and as a cavity liner. As such, its use as a fluoride agent for caries prevention is off label. However, there is a body of literature supporting its use for caries prevention and, on the basis of the evidence, this use is also recommended for children and adults in the American Dental Association Recommendations for Professional Topical Fluorides.<sup>7</sup> Similarly, there is literature supporting the use of silver diamine fluoride for caries arrestment, which is an off-label use because it is also cleared as a medical device for desensitization. From a medicolegal perspective, using a product off label when there is a paucity or lack of evidence of efficacy and safety places patients at risk and places the

BOX 4

**US Food and Drug Administration (FDA) resources list.**

INFORMATION	FDA WEBSITE
<b>FDA Basics</b>	<a href="http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm">http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm</a>
<b>Manufacturer and User Facility Device Experience</b>	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/textsearch.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/textsearch.cfm</a>
<b>510(k) Devices</b>	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm</a>
<b>Premarket Approval (Class III)</b>	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm</a>
<b>MedWatch Safety Alerts</b>	<a href="http://www.fda.gov/Safety/MedWatch/default.htm">http://www.fda.gov/Safety/MedWatch/default.htm</a>

dental professional at increased risk of (and in) a lawsuit.

**CHECKING THE PRODUCTS YOU USE ARE CLEARED OR APPROVED, AND WHY IT MATTERS**

It is possible you may want to check that a product you are using is FDA cleared or approved. An easy way to do this is to check on the FDA website using the brand name of the product (Box 4). This still does not ensure that the actual physical product you are using is legitimate. It could, for instance, be a gray-market product without your being aware of it. Gray-market products may be products that are sold in other countries and then imported and sold in the United States outside the normal distribution channels, often by “resellers.”<sup>8</sup> The product may not meet US laws and regulations and may have the same name as a legitimate product but be different, and the US distributor may be unaware of its existence. Nonetheless, dental professionals are responsible for their selection and use of products. Gray-market products can also be defective products that were intended to be destroyed but were diverted into the marketplace. In addition, manufacturers are not permitted to place a label stating “FDA cleared” or “FDA approved” on a device’s packaging or other materials, and seeing this on packaging should raise suspicions that the product may not be legitimate.

**REPORTING OR RESEARCHING ADVERSE EVENTS FOR PRODUCTS YOU USE OR RECOMMEND**

The FDA encourages dental and other health care professionals to report an observed or suspected product-related serious adverse events, errors, product-quality issues, and therapeutic failures through the FDA’s Medical Device Reporting (MDR).<sup>9</sup> This alerts the FDA to take any necessary action to ensure the health and safety of citizens. In addition, manufacturers are required to report to the FDA about devices that may have resulted in a serious adverse event (injury) or death, or that have malfunctioned and could in the future be associated with such events. There are also MDR requirements for importers and facilities. The FDA conducts adverse event analyses on the basis of the adverse-event reports it receives.

The process for reporting an adverse event is available on the FDA website (Box 4). To check for adverse events related to a product, a manufacturer and user facility device experience search on the website will provide this information and provide specifics on the number of adverse events for a given product and the nature of the adverse events.<sup>10</sup>

For the FDA’s Center for Devices and Radiological Health, 1 of its 2016-2017 strategic priorities is the establishment of an independent National Evaluation System for health Technology (NEST).<sup>11</sup> Using

large clinical database registries for adverse events would increase the availability of information from manufacturers, health care professionals, patients, and other stakeholders.<sup>12</sup> NEST would permit continuous monitoring of safety data and adverse events, resulting in the ability to improve surveillance to detect defective medical devices.<sup>11,13</sup> Conversely, NEST also would increase the amount of information available on the safety and efficacy of commercially available devices that would be supportive of new indications.<sup>11,13</sup>

**CONCLUSIONS**

The FDA determines product safety and efficacy by reviewing manufacturers’ submissions, and it verifies that data substantiate the intended product claims. In addition, the FDA conducts surveillance for products on the market and carries out inspections for GMP compliance. Mechanisms are also in place for adverse event reporting and for researching any adverse events with a particular product. Dental professionals, and the public, benefit from FDA oversight, which helps ensure patient and provider safety when using dental products. In summary, this is an important contribution to safer dental visits. ■

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