Oral Health Across the Agency

U.S. FOOD & DRUG ADMINISTRATION

Oral Health Across the Agency

The U.S. Food and Drug Administration (FDA) protects the public's health by ensuring the safety, efficacy, and security of a variety of products including human and veterinary drugs, biological products, and medical devices. Across its centers and offices, FDA's public health-focused mission also includes promoting and protecting the nation's oral health.

Reviewing and Approving Oral Health Product Applications

- FDA determines which new drugs (including therapeutic biologics), generic drugs and biosimilars, over-the-counter (OTC)/nonprescription drugs, and devices to prevent and treat oral health conditions are approved or cleared for use in the U.S. The agency's interdisciplinary staff—which includes dental professionals—provides clinical, nonclinical, and regulatory expertise to review submitted applications.
- FDA dentists also conduct pre- and postmarket safety reviews of drugs and devices that impact oral health, in accordance with regulatory law and policy—working collaboratively with engineers, chemists, biologists, statisticians, veterinarians, pharmacologists, physicians, and epidemiologists, among others.
- Center for Drug Evaluation and Research (CDER) dentists review the safety and efficacy of prescription and non-prescription drugs including fluoride containing dentifrices, anti-plaque/anti-gingivitis rinses, and other oral health care products. In addition to drugs that may directly target oral conditions or diseases, CDER dentists review drugs that work locally and/or systemically and are indicated for the treatment of non-dental diseases but which may be absorbed in or have impact on oral tissues and structures.

Over-the-Counter OTC | Nonprescription Drugs

OTC oral drugs may be marketed without an approved drug application under section 505 of the Food, Drug, and Cosmetic Act through the OTC drug monograph pathway. A monograph establishes active ingredients, uses (indications), doses, routes of administration, labeling, and testing under which a given therapeutic category is generally recognized as safe and effective. Examples of Monographs include: Anticaries Drug Products and Oral Healthcare Drug Products for Over-the-Counter Human Use.

- Center for Devices and Radiological Health (CDRH) dentists assess therapeutic devices, surgical devices, prosthetic devices, diagnostic devices, and dental equipment devices such as robotic devices, lasers, handpieces, restorative materials, treatment planning software, disease detection/diagnostic aids, tissue regeneration/augmentation bone grafts and membrane products, maxillofacial fixation and reconstruction systems, temporomandibular joint prostheses, dental implants and abutments, mouth rinses, and intraoral devices for obstructive sleep apnea and orthodontics.

Monitoring the Safety of Oral Health Products

- FDA dentists conduct safety surveillance, evaluating safety signals and medical device reports, and provide consultation regarding postmarket quality and compliance.
- Members of the public, health care professionals, and researchers can provide FDA with critical real-world data by reporting safety issues to the Safety Reporting Portal at: https://www.safetyreporting.hhs.gov/smarthub#. Dentists and other health scientists at FDA collect and analyze product-related adverse experience reports to identify and monitor safety signals. Additionally, they provide oversight of research studies to ensure protection of the welfare and rights of human participants.
- FDA collaborates with and supports external organizations, institutions, and data partners in performing scientific research, literature reviews, and analysis of real-world data aimed to address important issues in oral public health and dental product regulation, and activities that advance regulatory science through the development of new tools, standards, and approaches to assess safety, efficacy, quality, and performance of FDA-regulated products.

Tobacco Product Regulation and Oral Health

- Tobacco product use increases the risk of oral cancer, gum disease, tooth loss, tooth decay, burns in the mouth or lips, mouth sores, and other oral health problems. Center for Tobacco Products (CTP) dentists perform a crucial role in reviewing the health safety of new products applying for marketing authorization. Tobacco products under review include more than cigarettes; FDA has oversight of e-cigarettes (otherwise known as vapes or ENDS), cigars, and smokeless tobacco (such as chewing tobacco and oral nicotine pouches) to name a few.

FDA Oral Health Workgroup

- The FDA Oral Health Workgroup was formed in 2023 to promote cross-agency collaboration, share specialized expertise, and elevate the visibility of oral health issues to promote the agency's public health mission. Workgroup members—comprised of dentists and dental hygienists from CDER, CDRH, and CTP engage in monthly informational sessions, collaborative work products, and interprofessional collaboration to create collective impact.