

VIA ELECTRONIC FILING

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

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND THE FOOD AND DRUG ADMINISTRATION**

**CITIZEN PETITION**

***Request that The Commissioner of Food and Drugs Create a Public Database of Device  
Labels***

The undersigned submit this petition under 21 C.F.R. §§ 10.20, 10.25, 10.30, 800-898, 21 U.S.C. §§ 360c, 360j, and the Administrative Procedure Act.

**A. Action Requested**

The undersigned request that the Commissioner of the Food and Drug Administration and the Secretary of Health and Human Services (collectively “the FDA”) create a database of all labels, labeling, and instructions for use (collectively “device labels”) of FDA-regulated medical devices.

**B. Statement of Grounds**

This section explains the grounds for requested actions. Section 1 explains how the requested action aligns with the FDA’s mission and identifies the FDA’s statutory authority to regulate drug and device labels, focusing on both the express authority to regulate information included in a label and inherent authority necessary to keep the public informed. Section 2 discusses the public benefits created by a public database of device labels specifically for informed decision making, research, and postmarket enforcement. Finally, Section 3 summarizes the Petition’s request.

## 1. FDA’s Mission & Authority to Regulate Labels

The FDA’s mission is to promote and protect public health, in part by ensuring “there is reasonable assurance of the safety and effectiveness of devices intended for human use.”<sup>1</sup> This goal should be pursued “in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.”<sup>2</sup> Through the Commissioner of the FDA, the Secretary of Health and Human Services is responsible for “conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration.”<sup>3</sup>

To carry out this mission, the FDA has significant authority to regulate drug and device labels.<sup>4</sup> Drug labels contain crucial information about the drug, its intended use, contraindications, side effects, pharmacokinetics, dosage, and strength, as well as research supporting the approval, patient counseling, and instructions for use.<sup>5</sup> Medical device labels provide similar important information. For example, some surgical devices may have specific methods for use in specific patient populations and specific procedures—and the device may be contraindicated if used in a slightly different manner or on other patient populations.

The FDA also has inherent authority to “inform, announce, and apprise” the public, although its authority does not include the powers “to endorse, denounce, or advise.”<sup>6</sup> In the context of drugs, the FDA exercises this authority by maintaining a comprehensive public database of drug information (Drugs@FDA), including approval letters, drug packaging, and approved drug labels and labeling. In the context of devices, the FDA already maintains databases of all authorized devices and many decision letters (Devices@FDA), the latter of which contain only a thin description of the manufacturer’s indication for use. Although the FDA does publish labels of high-risk devices that receive premarket approval (PMA) following clinical trial data, it does not publish the vast majority of moderate- to low-risk devices cleared through the significantly less rigorous premarket notification 510(k) pathway.<sup>7</sup> In short, the FDA clearly has both express and inherent statutory authority to regulate device labels broadly and to create a device database specifically. It has already done so with respect to drugs; it should also do so in the case of medical devices.

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<sup>1</sup> 21 U.S.C. § 393(b).

<sup>2</sup> 21 U.S.C. § 393(b). <https://www.law.cornell.edu/uscode/text/21/393>

<sup>3</sup> 21 U.S.C. § 393(d)(2)(D).

<sup>4</sup> 21 U.S.C. §§ 321(m), 352, 355, 360c; 21 C.F.R. Part 801.

<sup>5</sup> David Simon, Michael Paasche-Orlow & Hooman Noorchashm, *Establishing Medical Device Transparency at the FDA—A Public Database for Device Labels*, JAMA vol. 334, no. 2 (July 8, 2025).

<sup>6</sup> *Apter v HHS*, 80 F.4th 579, 595 (5th Ct. App, 2023).

<sup>7</sup> Simon et al., *supra* note 5.

## 2. *Importance of a Public Device Label Database*

A public database of device labels would provide patients, clinicians, and health systems with important information about devices and their effects, encouraging better-informed decisions. Centralizing and publishing device label information could improve decision-making for physicians who report limited knowledge about the device review process. It could also improve patient decision-making.

A centralized database of all device labels—and all iterations of a given device’s labels—would also improve researchers’ ability to identify safety signals, evaluate the effects of existing regulations, and innovate. Just as with drug labels, device labels can provide clues for what safety signals researchers can expect to find in adverse events and insurance claims databases. The information can also be used to map firm innovations over time, measure firm responses to regulatory changes, and identify innovative uses of devices.

Finally, improving device label availability could bolster ex-post enforcement. Lawsuits against manufacturers for failing to disclose or misrepresenting risk information are based on the information provided in the device label. Access to consistent label data would allow the FDA and other regulators to link device-label information to adverse-event databases and more quickly identify potential manufacturer misconduct, billing irregularities, and personal-injury trends.

Creating a public device labels database would not exceed the authority that the FDA has already exercised in creating a public database for drug labels. Moreover, the FDA already maintains a public database at Devices@FDA of authorized devices and their associated decision letters. However, this database is not comprehensive and does not include the manufacturer IFU and all versions of updated IFUs for any given device. The agency would not need to collect new information in order to make device labels publicly available on the Devices@FDA database, as the agency already requires manufacturers to include proposed labeling materials when submitting a device for approval, and when new information emerges or regulatory actions are taken related to any given device. Adding device labels to the Devices@FDA database would support the FDA’s educational mission and promote public health by improving transparency and access to information by the research community and the public.

### 3. Summary of Request

The FDA has the ability and authority to create and maintain a device label database, which would serve the FDA's mission of promoting public health through information sharing, education, and the promotion of research. However, at present the FDA does not do so.

When manufacturers submit devices to the FDA for review, they must include a copy of the proposed labeling that conforms to federal regulations.<sup>8</sup> The undersigned request that when the FDA authorizes a device after reviewing, it post the authorized label and labeling, including instructions for use, in a public database, ideally folding it into the existing Devices@FDA database. Moreover, the undersigned request that the database also catalog the chronology of label changes, just as the FDA does for drugs. This would provide a valuable resource to easily understand a device's history that could be used by physicians, regulators, researchers, and firms.

#### **C. Environmental Impact**

Subject to Statutory Exemption

#### **D. Economic Impact**

This information can be furnished to the FDA Commissioner upon request.

#### **E. Certification**

The undersigned certify 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.

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/s/ David A. Simon

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<sup>8</sup> 21 CFR §§ 801, 807, 809.

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