



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

06/17/13  
→ HHS  
Aispach  
McWilliams  
Hayes

The Honorable Fred Upton  
Chairman  
Committee on Energy and Commerce  
House of Representatives  
Washington, D.C. 20515-6115

JUN 19 2013

Dear Mr. Chairman:

Thank you for your letter of April 9, 2013, cosigned by two of your colleagues, reiterating a request made by Rep. Griffith during the March 21, 2013, hearing before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, entitled "Health Information Technologies: Administration Perspectives on Innovation and Regulation." During that hearing, Rep. Griffith requested that Ms. Christy Foreman, witness for the Food and Drug Administration (FDA or the Agency), provide information to the Subcommittee regarding "technical input" that FDA provided to the Internal Revenue Service (IRS) regarding the medical device tax that was enacted as part of the Patient Protection and Affordable Care Act (Affordable Care Act).

During the course of the 2011-2012 IRS rulemaking implementing the excise tax on the sale of certain medical devices, the IRS requested, and FDA provided, technical input regarding FDA requirements applicable to medical devices and FDA staff's knowledge and understanding regarding how medical devices are commonly sold and used. Because this input was provided largely via teleconferences between the two agencies, FDA is providing the following summary to capture the nature of the input.

The IRS posed questions to FDA in the following areas:

- **What the Food, Drug, and Cosmetic Act (FD&C Act) definition of "device" does and does not cover.**
  - FDA explained the different prongs of the device definition at 21 U.S.C. 321(h) and the meaning of "intended use" under 21 *Code of Federal Regulations* (CFR) 801.4, and provided examples of products that FDA regulates as "devices."
- **How the device classification system works.**
  - FDA explained the three-tier classification scheme in section 513 of the FD&C Act, which is based on the level of regulatory control necessary to provide a reasonable assurance of safety and effectiveness of the device.

- FDA directed the IRS to the device classification regulations at 21 CFR parts 862-892, which identify all classified device types (noting that some device types have not yet been classified), and provided examples of devices in each class.
- FDA explained the Agency's use of "product codes" to further categorize devices within a classification and for device types for which there is no classification regulation.
- **FDA device listing requirements under 21 U.S.C. 360(j) (as implemented pursuant to 21 CFR part 807).**<sup>1</sup>
  - **How and when device establishment operators must list:** FDA explained that device establishment owners must list the devices they manufacture, prepare, propagate, compound, or process using FDA's electronic registration and listing system (FURLS), upon first going into business, and that they must update their information at least annually.
  - **Consequences for failing to list and FDA enforcement:** FDA explained that failure to list as required would cause the establishment owner's device to be misbranded under section 502(o) of the FD&C Act. This could result in the issuance of an Untitled Letter or Warning Letter to the firm and potential enforcement action, if not corrected, unless the device is subject to a policy of enforcement discretion, such as many mobile medical apps and certain other devices associated with health information technology.
  - **Exemptions for certain devices and entities:** FDA provided details regarding the exemptions<sup>2</sup> for devices intended for research or veterinary use and for components used in the manufacture/assembly of a device, and the exemptions for contract manufacturers and sterilizers that were terminated in mid-2012<sup>3</sup> pursuant to FDA revisions to 21 CFR part 807.
  - **Listing requirements applicable to special categories of devices:** FDA explained how listing requirements apply to combination products, convenience kits, and devices regulated by the Center for Biologics Evaluation and Research.

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<sup>1</sup> Once the IRS decided to tie the device tax to FDA device listing requirements, the IRS had a number of questions regarding the details and applicability of these requirements.

<sup>2</sup> See FDA, "Who Must Register, List and Pay the Fee," available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm>.

<sup>3</sup> FDA, "Implementation of Device Registration and Listing Requirements Enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Medical Device User Fee and Modernization Act of 2002, and Title II of the Food and Drug Administration Amendments Act of 2007," 77 *Federal Register* 45927 (Aug. 2, 2012), available at <http://www.gpo.gov/fdsys/pkg/FR-2012-08-02/pdf/2012-18764.pdf>.

- **Information that could help to inform IRS's interpretation of the "retail exception" under the Internal Revenue Code.<sup>4</sup>**
  - FDA explained that whether a device is, or is not, sold at retail is generally not relevant to FDA's regulatory scheme.
  - The IRS explored device classes, types, prescription versus over-the-counter, and "professional use" versus "home use" labeling as potential proxies to delineate which devices would be subject to the retail exception and which would not; FDA provided information regarding the nature of the devices in each of these categories.

Thank you, again, for contacting us concerning this matter. If you have further questions, please let us know. The same letter has been sent to your cosigners.

Sincerely,



Michele Mital  
Acting Associate Commissioner  
for Legislation

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<sup>4</sup> The IRS asked FDA for any knowledge pertaining to device sale and use that would help inform the IRS's interpretation of the provision in the Internal Revenue Code that exempts devices of a type that are "generally purchased by the general public at retail for individual use," referred to by the IRS as "the retail exception."