Insights: Alerts

FDA Moves Toward Online Database For Medical Device Info

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This past summer, the Food and Drug Administration (FDA) celebrated the 40th anniversary of the enactment of the Medical Device Amendments of 1976, which in part amended Section 510(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add requirements for the registration of device manufacturers and the listing of medical devices.

As enacted, the statute also required that the listings be accompanied by copies of the device label.[1] However, because the registration and listing information was required to be provided in paper form for many years, the FDA did not enforce the requirement that medical device establishments submit labeling information because "there was no practical way for FDA to compile, update, or access the information submitted on these forms, much less provide routine public access to the information." [2]

Therefore, the FDA decided to require by regulation that medical device manufacturers maintain a historical file of labels labeling, and advertisements for restricted devices, and "make all or part of that file available to FDA upon request." [3] This practice has remained in place since a final rule was issued in 1978.

In 2002, Congress began to recognize the impact of the internet when it passed the Medical Device User Fee and Modernization Act, providing the FDA with the authority to collect registrations and listings "at such time as FDA determined it was feasible ... through electronic means." [4] Amendments to the Medical Device User Fee Modernization Act in 2007 finally made the submission of registration and listing information by electronic means mandatory in all instances, unless a waiver is granted by the agency.

Now, almost 10 years after the requirements for electronic submission of registration and listing information, the FDA is issuing a proposed rule amending its regulations to require the electronic submission of the label and package insert for certain "home-use" medical devices when the devices are listed with the FDA. [5]

The proposed rule defines a "home-use" medical device as "a medical device that is labeled for use in any environment outside a professional health care facility." [6] The types of "home-use" devices that would be subject to the proposed rule, if finalized, are those that are regulated by the FDA as Class II or Class III devices, which are considered moderate-to-high-risk medical devices.[7]

The agency is planning to make the information available to the public through the internet, and intends to provide search tools that would enable the public to more easily locate information concerning a particular "home-use" device or a particular type of "home-use" device. [8]

The FDA notes that by limiting implementation to moderate-to-high-risk devices, the agency can focus on the type of medical devices for which "patients, caregivers, and health care professionals have a significant need for quick and easy access to information to help ensure a device can be used safely to achieve its intended health benefits."[9]

It will also help the FDA gain experience with the “receipt, archiving, and dissemination” of electronic labels and package inserts before the agency considers expanding the scope of the proposed rule to cover other types of medical devices.[10]

By providing public access to medical device labels and package inserts, the FDA can help ensure that patients and caregivers have access to the most current safety information and instructions for use for medical devices, even long after the device is no longer being marketed.

According to the FDA, there were over 800,000 adverse events associated with medical devices in 2014.[11] A review of those adverse events found that on average three to five of those reported events occurred in a home environment.[12]

While the agency does not make a specific link between the adverse events that occurred in the home as being caused even in part by missing labeling or instructions for use, the FDA believes that the proposed rule could help reduce the incidence of adverse events when the labeling is lost or misplaced and the user is “inexperienced” with the home-use device, “or when the labeling of the device has been updated with new information.” [13]

To that end, the FDA would establish an FDA-managed or partner internet web site that would provide a “consolidated and easily accessible source” that would include not only labeling for Class II and Class III home-use devices, but also approval or clearance status, intended uses, limitations, setup and operation.[14] Below are some highlights of the proposed rule:

- Establishment and listing regulations are amended to require that the label and package information be submitted electronically for Class II and Class III home-use medical devices.
- Label and package insert information would be submitted whenever a medical device establishment is required to submit or update listing information.
- The rule would “limit” the definition of “package insert” to include only those information materials directed to the intended user of the device and that are included in the device package. The proposed rule does not require the submission of advertisements or other labeling and would not require any changes to the content of home-use device labeling.
- Initially, the FDA expects to require that label and package inserts be submitted as PDF files. However, the agency expects to transition to requiring the information to be submitted in SPL format.
- The failure to provide the required labeling information would cause the device to be misbranded per section 502(o) of the FD&C Act.
- The proposed rule does not apply to devices intended for use in professional health care facilities.

If finalized, the proposed rule does not appear to place any significant additional burdens on medical device establishment owners or operators because no changes are proposed for the information that is already required to be included in the packaging of “home-use” medical devices.

Assuming that the FDA is able to create a user friendly database, access to current labeling and instructions for use of Class II and Class III “home-use” medical devices will most likely be beneficial to users of such devices. Comments to the proposed rule were due by January 17, 2017.

[1] See Section 510(j)(1)(B)(ii) of the FD&C Act.

[2] See Proposed Rule 81 Fed. Reg. 71,415, 71,417 (October 17, 2016).

[3] Id. at 71, 417 citing to 42 Fed. Reg. 52808 at 52809 (September 30, 1977).

[4] Id.

[5] Id.

[6] See Proposed 21 C.F.R. § 807.200.

[7] The proposed rule does not apply to devices regulated by the Center for Biologics Evaluation and Research (CBER). See Proposed Rule at 71,417.

[8] See Proposed Rule at 71,415.

[9] Id. at 71,418.

[10] Id.

[11] Id.

[12] Id.

[13] Id.

[14] Id. at 71,419.