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FDA Alert

On October 17, 2016, FDA issued a proposed rule, *Electronic Submission of Labeling for Certain Home-Use Medical Devices*, which, if finalized, would require electronic submission of the device label and package insert of certain home-use devices. This is the next step in the agency’s home-use devices initiative program and follows a November 2014 guidance, *Guidance for Industry and Food and Drug Administration Staff: Design Considerations for Devices Intended for Home Use*, related to the design, testing, and labeling of home-use devices, and a previous limited pilot program for electronic submission of home-use medical device labeling.

FDA’s proposed rule, if finalized, would require electronic submissions of "required" patient labeling (e.g., device labels, package insert or instructions for use (IFU)) for class II and class III medical devices intended for home use (e.g., blood glucose meters). This labeling will be maintained in an online repository and be available to the public. The goal of this effort is to provide increased access to home-use device labeling to prevent misuse and associated adverse events due to lost or misplaced labeling and operating instructions. The proposed rule does not apply to other types of labeling not addressing the operation and use of the device such as promotional labeling and advertisements, and is not intended as a means for agency review of home-use device labels or package inserts.

Under the proposed rule, electronic labeling would need to be submitted for class II and class III devices labeled for use outside a professional healthcare facility. This would include devices that are sold over-the-counter, as well as those intended for physician-directed use available only under a prescription and devices which can be used at home by non-medical caregivers. The proposed rule would also allow for electronic submission of device labels and package inserts for class I home-use devices or other home-use devices on a voluntary basis.

Electronic labeling would be required from anyone listing such a device in FDA’s FURLS database. Due to private labeling and relabeling, it is common for multiple entities to list the same device, but under the proposed rule each would need to supply electronic labeling. However, given that it is not always clear to a user that the private labeled or relabeled device is identical to another device particularly as there may be differences in the labeling, this requirement appears
consistent with FDA's overall goals. As applied to contract manufacturers or reprocessors, this requirement may result in multiple companies needing to supply the identical labeling. Thus, it may ultimately make sense for the final rule to be narrower than requiring the submission of labeling from any entity listing a home use device.

The proposed rule would require the label and package insert of a home-use device to be submitted whenever any provision within 21 CFR Part 807 requires listing information to be submitted or updated. Thus, when a company first lists a new home-use device, they would also need to supply the electronic labeling. New labeling would then be required each time the listing information is updated with FDA, which is typically annually, or the company could certify that no modifications to the labeling were made. An updated label or package insert could also be submitted voluntarily at any time.

In proposing this rule, FDA discusses the increasing reliance on electronic submissions. While this initial proposed rule is limited to electronic submission of labeling for higher risk medical devices, excluding class I medical devices and products regulated by the Center for Biologics Evaluation and Research (CBER), the proposed rule contemplates expansion of this electronic submission program in the future. Over time, and as resources permit, FDA plans to expand the database to provide links to information available in other FDA databases, such as the device identifier required by FDA's unique device identification (UDI) system, FDA premarket submission numbers, adverse event reports, and public health notifications. Further, it remains to be seen whether FDA will continue to require the submission of paper copies of labeling going forward. For now, however, the proposed rule states that electronic submission of labeling information does not replace the submission of such information in premarket submissions. In addition, FDA currently requires that all home-use devices be supplied to the end user with paper labeling, which has been challenging for some companies, particularly manufacturers of standalone software that is downloaded from the internet. It is unclear whether this electronic labeling submission would alter that requirement.

Comments are being accepted on the proposed rule through January 17, 2017. While comments on all aspects of the rule are welcome, FDA is specifically interested in comments on the following topics:

1. Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;
2. The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Ways to enhance the quality, utility, and clarity of the information to be collected;
4. Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.
If you would like to submit comments on these issues or other aspects of the proposed rule, Hogan Lovells would be pleased to assist in the preparation of comments.

Contacts

Jennifer Agraz Henderson
Partner

Lina R. Kontos
Partner

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