UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Device Labeling

OMB Control Nos. 0910-0485, 0910-0577, and 0910-0740

Request for Non-substantive Change and Request to Discontinue:

Statutory provisions in section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibit the misbranding of medical devices and govern content and format requirements for product labeling. Agency regulations in 21 CFR part 801 set forth specific data elements for medical device product labeling including information that must be disclosed to consumers. Section 502 of the FD&C Act also provides that if an original single-use-device (SUD), or an attachment to it, prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol in a prominent and conspicuous manner. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record. To help implement these provisions and communicate FDA's thinking in this regard, we developed the guidance document entitled "*Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended--Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices*" (May 2006), available from our website at https://www.fda.gov/media/71187/download. The guidance document is intended to identify circumstances in which the name or symbol of the original SUD manufacturer is not prominent and conspicuous, as used in section 502(u) of the FD&C Act. Information collection discussed in the guidance is currently approved under OMB control no. 0910-0577.

We also developed the guidance document entitled, "*Medical Devices: Use of Certain Symbols in Labeling--Glossary to Support the Use of Symbols in Labeling*" (November 2004), available from our website at file:///C:/Users/DHC/AppData/Local/Temp/3/MicrosoftEdgeDownloads/fc9afdd6-1cd5-4568-aab6-27e41306e4fb/FDA-2013-N-0125-0021_content.pdf. The guidance provides information on the use of selected symbols in place of text to convey certain information required for in vitro diagnostic devices (IVDs) intended for professional use, but not for over-the-counter or prescription home-use IVDs. Information collection associated with the guidance is currently approved under OMB control no. 0910-0740.

Both guidance documents were developed consistent with our Good Guidance Practice regulations in 21 CFR part 10.115, which provide for public comment at any time. For efficiency of agency operations, we are consolidating burden we attribute to the referenced guidance documents with burden we attribute to information collection associated with the statutory and regulatory requirements currently approved in OMB control no. 0910-0485. We have increased the annual number of responses by 3,952 and the annual number of burden hours by 15,095 to reflect these adjustments. Publication of a 60-day notice soliciting public comment on all elements of the information collection, including the consolidation and burden adjustments, is currently underway. Upon approval of this request, we intend to discontinue OMB control nos. 0910-0577 and 0910-0740.

Submitted: June 2021