UNITED STATES FOOD & DRUG ADMINISTRATION-

OMB Control No. 0910-0485: Medical Device Labeling Requirements
Specific Labeling for Certain Devices

Request for Non-Substantive/Non-Material Change:

This information collection helps support implementation of medical device labeling requirements governed by section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352), codified in FDA regulations, and discussed in agency guidance. Medical device labeling requirements provide for the label or labeling of a medical device so that it is not misbranded and subject to regulatory action. Certain provisions under section 502 require manufacturers, importers, and distributors of medical devices to disclose information about themselves or the devices on the labels or labeling for the devices. Regulations in parts 800, 801, and 809, and associated regulations in parts 660 and 1040 (21 CFR parts 660, 800, 801, 809 and 1040) set forth content and format requirements manufacturers, importers, and distributors of medical devices must disclose about themselves or the devices, on the label or labeling for the devices to health professionals and consumers.

For operational efficiency, we are requesting to consolidate burden we attribute to labeling recommendations found in the guidance document, "*Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300 - Class II Special Controls Guidance for Industry and FDA Staff*," (December 2008) currently approved in control number 0910-0633. While the guidance document provides examples of labeling recommended to meet the requirement of special controls for latex condoms under 21 CFR 884.5300(b)(2), it also communicates that there are other specific labeling requirements for latex condoms contained in 21 CFR 801.435 (user labeling for latex condoms), and 21 CFR 801.437 (user labeling for devices that contain natural rubber). To account for the annual 5 responses and 60 hours we attribute to the recommended labeling activities discussed in the guidance document, we have established the IC element "*Specific Labeling for Certain Devices – Natural Rubber Latex Condoms."* As other label-specific guidance documents may be issued and appropriate for inclusion in the information collection, we intend to organize them within this collection element. Upon approval of this request, we intend to discontinue the collection of information currently approved under OMB control number 0910-0633.

Submitted: August 2023