4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 1002, 1010, and 1040

[Docket Nos. FDA-2011-N-0070 and FDA-2016-N-2491]

RIN 0910-AG79 and 0910-AF87

Withdrawal of the Laser Products; Proposed Amendment to Performance Standard and the Electronic Submission of Labeling for Certain Home-Use Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, Agency, we) is announcing the withdrawal of two proposed rules that published in the *Federal Register*. These proposed rules are not currently considered viable candidates for final action. FDA is taking this action because these proposed rules need to be reconsidered based on public comments received and new information developed after the publication of the proposed rules.

DATES: As of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], the proposed rules published on June 24, 2013, at 78 FR 37723, and October 17, 2016, at 81 FR 71415 are withdrawn.

ADDRESSES: For access to the docket, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5518, Silver Spring, MD 20993-0002, 301-796-5837, Madhusoodana.Nambiar@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

In 1990, FDA began a process of periodically conducting comprehensive reviews of its regulation process, including reviewing the backlog of proposed rulemakings that had not been finalized. As FDA removed many proposed rules not finalized, the Agency implemented a process of reviewing existing proposed rules every 5 years.

As part of this process and the Agency's regulatory reform initiative, we continue to conduct reviews of existing proposed rules. The review determines if the proposals are outdated, unnecessary, or should be revised to reduce regulatory burden while allowing FDA to achieve our public health mission and fulfill statutory obligations.

As part of these efforts, FDA is withdrawing the following proposed rules:

	Title of Proposed Rule	Publication Date, *Federal Register* Citation	Docket No.	Reason for Withdrawal
1	Laser Products; Proposed Amendment to Performance Standard	June 24, 2013, 78 FR 37723	FDA-2011-N-0070	The proposed rule referenced an international performance standard. That international standard is now being revised to reflect advancements in technology. FDA wants to have the most current international standard as a reference before publishing a final rule on laser products.
2	Electronic Submission of Labeling for Certain Home-Use Medical Devices	October 17, 2016, 81 FR 71415	FDA-2016-N-2491	Several adverse comments challenged the proposed FDA-managed labeling database as being unduly burdensome on both FDA and on industry, without efficiently enhancing public health. Additionally, concerns regarding the proposed

				format and potential costs for industry to fully implement were also raised. Based on the adverse comments, this rulemaking would benefit from being withdrawn at this time and reconsidered. The Agency plans to reconsider its approach and solicit further public input at a future date.

The withdrawal of these proposals identified in this document does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposals listed in the chart. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment. Furthermore, this withdrawal of the proposed rules is only intended to address the specific actions identified in this document, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn proposed rules, you may review the Agency's website (https://www.fda.gov) for any current information on the matter.

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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