CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

May 24, 2022

Submitted via www.regulations.gov

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Medical Devices; Quality System Regulation Amendments; Proposed Rule; 87 *Fed. Reg.* 10119-10134. Docket No. FDA–2021–N–0507.

Dear Sir or Madam:

The Consumer Healthcare Products Association[1] ("CHPA") submits these comments in response to the U.S. Food and Drug Administration's ("FDA's" or the "Agency's") request for stakeholder input on the proposed rule "Medical Devices; Quality System Regulation Amendments" ("Proposed Rule").[2] The Proposed Rule would revise the current Quality System Regulation (QSR) at 21 CFR Part 820 to replace the substantive quality system requirements with an incorporation by reference of the quality system management requirements in ISO 13485, with the revised 21 CFR Part 820 referred to as the Quality Management System Regulation (QMSR). For more than 141 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of OTC medical products. CHPA members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

CHPA supports FDA's efforts to harmonize the current Quality System Regulation in 21 CFR Part 820 with the international quality management system requirements used by regulatory authorities from other jurisdictions and generally agrees with the Proposed Rule's approach of incorporating ISO 13485. However, CHPA recommends

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

[2] FDA, Medical Devices; Quality System Regulation Amendments; Proposed Rule, 87 *Fed. Reg.* 10119-10134 (February 23, 2022). Accessed from https://www.govinfo.gov/content/pkg/FR-2022-02-23/pdf/2022-03227.pdf on May 10, 2022.

that FDA address several points of concern or clarification when finalizing the Proposed Rule, as discussed below.

First, CHPA appreciates that FDA is planning to provide a transition period to allow manufacturers adequate time to make changes necessary to comply with the new requirements. However, CHPA is concerned that 1 year may not be sufficient time for companies that are not currently compliant with ISO 13485 to transition their quality system and requests that FDA provide for a 36-month transition period. This transition period would be consistent with the transition period provided for compliance under ISO 13485 following the issuance of the 2016 version. Although many global manufacturers are familiar with ISO 13485 and the standard is similar in many respects to the current QSR in 21 CFR Part 820, transitioning may nonetheless take more than 1 year. As an initial matter, some manufacturers that do not distribute devices globally may not be familiar with ISO 13485 and will need time to understand the differences between the QSR and ISO 13485 and the necessary substantive revisions to their quality system approach and procedures. Even where ISO 13485 and the current QSR impose similar substantive requirements, manufacturers will need to update numerous quality system procedures, forms, and related documents to revise references to sections of the QSR to the relevant portions of ISO 13485. Further, as described in the Proposed Rule, ISO 13485 places greater emphasis on risk management and risk-based decision-making than the QSR. Accordingly, ISO 13485 more expressly incorporates risk analysis throughout the quality system, whereas the QSR identifies risk analysis only in design validation. To comply with the new QMSR, companies will need to embed risk management in all quality activities and update procedures. Once the relevant processes and procedures have been revised, manufacturers will need to conduct training on the revised procedures. Therefore, CHPA requests that FDA include in the final rule a 36-month transition period to allow manufacturers sufficient time to implement compliance with ISO 13485 and the new QMSR.

Second, CHPA recommends that FDA include in the final QMSR a provision consistent with current 21 CFR 820.180(c). Under current 21 CFR 820.180(c), FDA will not review, during a routine inspection management review, reports (required by current 21 CFR 820.20(c)), internal quality audit reports (under current 21 CFR 820.22), and supplier audit reports (under current 21 CFR 920.50(a)). Management review, internal audits, and supplier audits are required under ISO 13485, but the Proposed Rule does not address whether such reports would remain out of scope in an FDA inspection or whether FDA now proposes to include these records in its review during an inspection. When issuing the final rule for the current 21 CFR Part 820, FDA agreed with comments that making supplier audit reports and other internal audit reports subject to FDA review could negatively impact supplier relationships or the usefulness of internal audits as a self-inspection tool.[3] CHPA believes it remains appropriate for FDA to

[3] FDA, Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52602, 52625, 52637 (Oct. 7, 1996). Accessed from

exclude these records from review during routine inspections and recommends that FDA incorporate the exception in current 21 CFR 820.180(c) into the final QMSR.

Third, CHPA requests that FDA clarify the scope of requirements that would apply under the requirement in clause 4.2.5 of ISO 13485 to "define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements." Proposed 21 CFR 820.10 includes several clarifications regarding "applicable regulatory requirements" referenced in ISO 13485, but does not address this requirement of clause 4.2.5 of ISO 13485. Because protection of confidential health information is not addressed in the current QSR, and "confidential health information" is not defined in ISO 13485, this clause could create confusion as to the Agency's expectations for how device manufacturers will demonstrate compliance with this clause and the scope of any "applicable regulatory requirements." CHPA requests that when finalizing the QMSR, FDA clarify that in the US data privacy and the protection of health information are subject to separate legal frameworks that are not administered by FDA and that the Agency would not review a device manufacturer's compliance with these frameworks during inspections under the QMSR.

Fourth, CHPA requests that FDA clarify whether it is also incorporating by reference into the new QMSR the additional ISO standards that are referenced in ISO 13485. For example, ISO 13485 references ISO 14971 "Medical Devices—Application of Risk Management to Medical Devices." While the Proposed Rule discusses that ISO 13485 places greater emphasis on risk management than the current QSR, the Proposed Rule does not address whether FDA would expect device manufacturers to comply with ISO 14971 under the QMSR. Likewise, Clause 8.2.4 Internal Audit of ISO 13485 references ISO 19011 "Guidelines for auditing management systems." CHPA requests that FDA clarify that the Agency is only incorporating by reference into the QMSR ISO 13485 and that other ISO standards referenced in ISO 13485 are not incorporated into the QMSR.

Fifth, CHPA requests that FDA clarify the impact of future revisions to ISO 13485 to the new QMSR under the Proposed Rule. The Proposed Rule incorporates by reference the third edition of ISO 13485, dated March 2016. However, the ISO 13485 standard is updated periodically and FDA has not explained in the Proposed Rule how any such revisions would impact compliance with the QMSR. CHPA requests that FDA clarify that should the ISO 13485 standard be revised and FDA wish to incorporate the revised ISO 13485 standard into the QMSR, FDA would do so through rulemaking to revise 21 CFR Part 820. We also request that FDA clarify that any revisions to Part 820 to incorporate revisions to ISO 13485 would include an appropriate transition period for manufacturers to implement compliance with the revised ISO 13485 standard

---

https://www.govinfo.gov/content/pkg/FR-1996-10-07/pdf/FR-1996-10-07.pdf on May 23, 2022.; FDA, Regulations Establishing Good Manufacturing Practices for the Manufacturing, Packing, Storage, and Installation of Medical Devices, Final Rule, 43 Fed. Reg. 31508, 31510 (July 21, 1978). Accessed from https://www.govinfo.gov/content/pkg/FR-1978-07-21/pdf/FR-1978-07-21.pdf on May 23, 2022.

reflecting the nature of the changes. CHPA also recommends that FDA provide guidance on the planned implementation time period for both minor updates to ISO 13485 as well as significant revisions to the standard.

* * *

CHPA appreciates the opportunity to provide suggestions to the Agency as it amends the current Quality Systems regulations, through incorporation of ISO 13485 by reference, to more closely align with international consensus standards for devices. Please do not hesitate to contact us if you have any questions about our comments.

Respectfully Submitted,

Marcia D. Howard, Ph.D., CAE

Digitally signed by Marcia D. Howard, Ph.D., CAE
Date: 2022.05.24 10:03:32 -04'00'

Marcia D. Howard, Ph.D., CAE
Vice President, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

Cc: Keisha Thomas and Melissa Torres, CDRH (sent via email to Proposed-Device-QMSR-Rule@fda.hhs.gov, Keisha.Thomas@fda.hhs.gov; and Melissa.Torres@fda.hhs.gov)

S:\Medical Devices\CMD Committee\FDA Submissions\Pt 820 Regulations Amendment\FINAL\CHPA Comments_FDA Proposed Rule_Part 820_ISO13485_Amendment_FINAL 05.24.2022.docx