CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

February 21, 2024

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: Proposed Rule, Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes; 88 *Fed. Reg*. 83774 - 83802 (Nov. 30, 2023); Docket No. FDA-2023–N–3392[1]

Dear Sir or Madam:

The Consumer Healthcare Products Association[2] ("CHPA") submits these comments on the Proposed Rule entitled Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes ("Proposed Rule"). For more than 143 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 understands that the Proposed Rule affects products that are currently regulated as unclassified devices subject to 510(k) premarket notification requirements under product codes FRO, GER, MGP, MGQ, and EFQ, and would establish three new classification regulations for these product codes, classifying the devices into either class II or class III. CHPA further understands that wound dressings and liquid wound washes that achieve the maintenance of a moist wound environment through chemical action may be drugs or combination products, and are outside the scope of the Proposed Rule. Accordingly wound dressings with antimicrobials that make wound management claims, such as treatment of wounds/wound infection, would not be within the scope of the Proposed Rule.

CHPA requests that the Agency clarify how the products that are currently unclassified and that are not within the scope of the Proposed Rule would be regulated when the Proposed Rule is finalized.

---

[1] Food and Drug Administration Medical Devices; General Plastics and Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes; Proposed Rule (88 *Fed. Reg.* 83774 – 83802). Accessed from https://www.govinfo.gov/content/pkg/FR-2023-11-30/pdf/2023-26209.pdf on February 6, 2024.

[2] 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.

The preamble to the Proposed Rule explains that after the "proposed rule is finalized and the classification becomes effective, such products could be subject to a different type of marketing authorization, depending on the product claims. For example, products containing antimicrobials that make certain wound managements claims may be considered combination products or drugs and regulated as such."[3] Based on the Proposed Rule, CHPA understands that those products currently under product codes FRO, GER, MGP, MGQ, and EFQ that "are not within scope of th[e] proposed rule [. . .] will be addressed via a separate classification action."[4] Finally, the Proposed Rule states that wound dressings that are outside the scope of the Proposed Rule and classification action "because they are currently regulated [. . .] as a distinct category within the product code FRO" will be assigned a new product code.[5]

In light of these statements, CHPA requests clarification regarding how products that are currently marketed under product codes FRO, GER, MGP, MGQ, and EFQ and that are not within the scope of the Proposed Rule will be affected by the finalization of the Proposed Rule. That is, can these products continue to be marketed as unclassified devices under their existing 510(k) clearances unless and until they are addressed in a separate classification regulatory action? It appears that at least for products under FRO that are outside the scope of the Proposed Rule, FDA intends to issue a new product code. Can FDA confirm that this will be an administrative step (*i.e.*, updating the product code in FDA's establishment registration and listing and 510(k) databases to reflect a subsequent or new product code) that will not require any action on behalf of the sponsor and will not affect the continued marketing of products under FRO that are not within the scope of the Proposed Rule?

CHPA would also like to understand how the Agency plans to treat products with "other chemicals" that are not listed in Table 3 in the Proposed Rule or otherwise included within the scope of the Proposed Rule. Assuming a product that is currently classified under product codes FRO, GER, MGP, MGQ, and EFQ contains an ingredient that works through chemical action, would the future classification action maintain the device-led combination product status for the product? Or could a product that is currently cleared under FRO be regulated as a drug in the future and if so, under what circumstances?

CHPA also requests clarification on the process for continued marketing of products that are affected by the Proposed Rule and that FDA intends to classify into class II. In the Proposed Rule, FDA states that for "[d]evices proposed to be classified into class II that have prior 510(k) Clearance," the Agency "proposes that it would accept a new 510(k) and would issue a new clearance letter, as appropriate, indicating substantial equivalence and compliance with the special controls."[6] It is unclear whether the Agency is contemplating a new submission to FDA, or whether the previous 510(k) would simply be converted into a new clearance, and CHPA requests clarification from FDA on the process. In case a new submission is required, CHPA would like to confirm whether FDA would expect a full 510(k) submission or a more limited submission that is focused on demonstrating compliance with the newly established special controls (to the extent not addressed in the prior clearance). In the latter scenario (which CHPA supports), sponsors would provide data or information only to address the special controls and would certify that there are no other changes from the prior 510(k) clearance, allowing FDA to convert the previous 510(k) into a

[3] 88 *Fed. Reg.* 83774, 83775 (Nov. 30, 2023), fn. 1.
[4] *Id.* at 83777, fn. 8 through fn. 12.
[5] *Id.* at 83784, fn. 21 and fn. 24.
[6] *Id.* at 83793.

new clearance. Finally, CHPA would like to clarify if new user fees would apply to the submission (whether a full 510(k) or a more limited submission).

CHPA also requests clarification regarding the Agency's statement that "the special controls become effective 6 months after the effective date of the rule, when finalized," and that the Agency may take enforcement after that date if a manufacturer markets a device that does not comply with the special controls.[7] CHPA requests clarification whether FDA intends to provide 6 months of enforcement discretion after the effective date of the final rule to allow the continued marketing of devices under product codes FRO, GER, MGP, MGQ, and EFQ under the existing 510(k) clearances.

CHPA appreciates the opportunity to provide comments to the Agency on the Proposed Rule. Please do not hesitate to contact us if you have any questions.

Respectfully Submitted,

Marcia D. Howard, Ph.D., CAE

Digitally signed by Marcia D. Howard, Ph.D., CAE
Date: 2024.02.21 15:41:57 -05'00'

Marcia D. Howard, Ph.D., CAE
Vice President, Regulatory & Scientific Affairs
Consumer Healthcare Products Association
Email: mhoward@chpa.org
Phone: 202 429 3532 (office)

Cc: Brandon Kitchel, CDRH (via email at brandon.kitchel@fda.hhs.gov)

[7] *Id.*