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November 14, 2023

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

Re: Proposed Rule, Medical Devices; Laboratory Developed Tests;
88 *Fed. Reg*. 68006-68031 (Oct. 3, 2023); Docket No. FDA-2023-N-2177[1]

Dear Sir or Madam:

The Consumer Healthcare Products Association[2] ("CHPA") submits these comments on the Proposed Rule entitled Medical Devices; Laboratory Developed Tests ("Proposed Rule"). For more than 142 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.

In the Proposed Rule, FDA is "proposing to amend its regulations to make explicit that *in vitro* diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory."[3] The Proposed Rule would have the effect of regulating as IVDs laboratory developed tests (LDTs), which the Agency currently does not regulate as medical devices, and the Proposed Rule is accompanied by a policy under which FDA intends to phase in regulatory requirements for LDTs.

CHPA requests the Agency's confirmation that the Proposed Rule does not affect laboratory tests that are general wellness products and that are either carved out from

[1] FDA Medical Devices; Laboratory Developed Tests; Proposed Rule; 88 *Fed. Reg.* 68006-68031 (October 3, 2023). Accessed from https://www.govinfo.gov/content/pkg/FR-2023-10-03/pdf/2023-21662.pdf on November 1, 2023.

[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.

[3] 88 Fed. Reg. at 68006.

the device definition under sections 201(h) and 520(o)(1) of the FD&C Act[4] or are subject to enforcement discretion under CDRH's[5] general wellness policy for low risk wellness products.[6] That is, if a test is currently developed and manufactured in a laboratory and meets the definition of a general wellness product (and is not subject to FDA oversight), the Proposed Rule would not affect the test's status as a general wellness product and would not subject the test to medical device regulatory requirements or impact the developer's ability to market the product without premarket review.

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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
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Cc: Toby Lowe, CDRH (sent via email to LDTProposedRule@fda.hhs.gov and Toby.Lowe@fda.hhs.gov)

[4] Section 520(o)(1)(B) of the FD&C Act states that software that is intended "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition" is not a device under section 201(h) of the FD&C Act.

[5] U.S. Food and Drug Administration Center for Devices and Radiological Health.

[6] Guidance for Industry and Food and Drug Administration Staff, General Wellness: Policy for Low Risk Devices (Sept. 27, 2019). Accessed from https://www.fda.gov/media/90652/download on November 14, 2023.