American Pharmacists Association

**Via Electronic Submission to: www.regulations.gov**

May 17, 2021

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

**Re: Docket No. FDA–2021–Z–0025: Medical Devices; Class I Surgeon's and Patient Examination Gloves**

Dear Sir or Madam:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Food and Drug Administration (FDA) on Medical Devices; Class I Surgeon's and Patient Examination Gloves, published in the Federal Register on April 16, 2021 (86 FR 20167). Founded in 1852, APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

Medical gloves are used by healthcare providers – including pharmacists -- to prevent the spread of infection or illness. As such, it is critical for medical gloves to be safe and effective for their intended purpose. **Accordingly, APhA supports FDA's determination in its April 16, 2021 notice that the six types of reserved class I patient examination gloves with the product codes LYY, LYZ, OIG, OPC, OPH, and LZC, and one type of reserved class I surgeon's glove with the product code OPA identified in the January 15, 2021 notice (86 FR 4088) require a 510(k) premarket notification under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c).** APhA agrees with FDA's determination that the Department of Health and Human Services' (HHS) finding that these seven class I medical gloves no longer require 510(k) premarket notification lacks adequate legal and scientific support.

2215 Constitution Ave. NW
Washington, DC 20037
800 237 2742
pharmacist.com

As FDA points out, HHS failed to explain how it determined that the medical gloves no longer meet the statutory standard, i.e., that the gloves are not intended for a use that is of substantial importance in preventing impairment of human health, or do not present a potential unreasonable risk of illness or injury. On the contrary, these patient examination gloves and surgeon's gloves are critical to preventing contamination and protecting healthcare providers – including pharmacists – and patients from the spread of infectious diseases such as hepatitis, HIV, and others.

HHS also failed to take into account FDA's experience in reviewing 510(k)s for these medical gloves or the products' recall history. Instead, HHS inappropriately based its decision only on its evaluation of adverse events reported to FDA's Manufacturer and User Facility Device Experience (MAUDE) database from March 30, 2020 until November 30, 2020, when adverse event reporting may have been limited due to the COVID-19 pandemic. As FDA notes, "adverse event data is not adequate on its own for assessing safety, let alone whether to determine a device to be exempt from 510(k)."[1]

Finally, and perhaps most troubling, FDA did not find any evidence that HHS consulted with or otherwise involved the agency in its exemption determination or issuance of the January 15, 2021 notice, in contravention of Section 1003(d) of the FD&C Act (21 U.S.C. 393(d)) providing that the Secretary ''shall be responsible for executing'' the FD&C Act ''through the [FDA] Commissioner.'' In this case involving provider and patient safety, it is critical for HHS to consult with and have the benefit of FDA's expertise in evaluating whether particular devices such as these medical gloves can be exempted from 510(k) premarket notification requirements.

Conclusion

Thank you for the opportunity to provide these comments in support of FDA's determination that the seven class I medical gloves identified in the January 15, 2021 notice require 510(k) premarket notification.

[1] 86 FR 20167, p. 20171.

APhA
American Pharmacists Association

If you have any questions or require additional information, please contact Karin Bolte, Director, Health Policy, at kbolte@aphanet.org or by phone at (202) 558-2727.

Sincerely,

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs

2215 Constitution Ave. NW
Washington, DC 20037

800 237 2742
pharmacist.com