James N. Czaban
Partner, FDA Practice Group
Loeb & Loeb, LLP
901 New York Avenue NW
3rd Floor East
Washington DC 20001-4432

Sent via email to: jczaban@loeb.com

Re: Citizen Petition – Docket Number FDA-2020-P-2289

Dear Petitioner:

This is an interim response to the petition dated December 10, 2020, filed by the Food and Drug Administration (FDA) on December 11, 2020. In the petition, you requested that the FDA publish a new or amended regulation, Guidance document, and/or in the interim an Advisory Opinion, setting forth the following policies:

1) That garments described and referred to herein as "Daily-Wear Uniform Scrubs," which are marketed to and worn by workers in healthcare facilities and settings, including physicians, nurses, medical technicians, orderlies, and other staff members, are not medical "devices" within the meaning of the FDCA and FDA regulations and are not regulated by the FDA when the following circumstances are applicable:

    - The scrubs are intended for every day wear as a general work uniform by personnel in healthcare settings such as hospitals, medical and dental offices, veterinary clinics, clinical laboratories, etc.

    - The scrubs are not labeled or marketed with claims that the garment will diagnose, treat, cure, prevent, or mitigate any disease, or that the scrubs will affect the structure or function of the body of the wearer or any other person with whom the wearer comes into contact; and

    - The scrubs are not intended, labeled or marketed for surgical use or with claims identified in FDA's "Surgical Apparel" regulation, 21 C.F.R. § 878.4040;

2) That Daily-Wear Uniform Scrubs described in Request No. 1. also are not "devices" and are not regulated by the FDA when the following additional circumstances are applicable:

    - The scrubs are manufactured with an EPA-registered antimicrobial ingredient as a component of the garment;

- The antimicrobial component is solely intended, and is only described in labeling, marketing and promotional materials, for non-medical purposes, such as protecting the garment itself and/or enhancing the wearability or durability of the garment by, for example, reducing the accumulation of odors, resisting stains, protecting against color fading, and similar purposes; and

- The scrubs are not labeled or marketed with claims referencing any specific pathogen, virus, or infectious agent, or with claims that the garment will prevent, control, or reduce the spread of any infectious or communicable disease.

You further request that:

3) FDA refrain from issuing any Warning Letter, Untitled Letter, or "It Has Come to Our Attention" (IHCTOA) Letter, or from initiating any other form of enforcement action, against any manufacturer or marketer of Daily-Wear Uniform Scrubs described in Request No. 1, or Antimicrobial Daily-Wear Uniform Scrubs identified in Request No. 2, unless and until at least 180 days after FDA has issued a complete substantive response denying the requests made herein, fully explaining the agency's legal bases for asserting regulatory jurisdiction over such products, and specifically identifying such response as a "final agency action" within the meaning of the Administrative Procedure Act, 5 U.S.C. § 704.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations (21 CFR 10.30(e)(2) and 821.2). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Andrew Yeatts, Ph.D. of our Office of Policy at (301) 796-4539.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2021.05.19 12:55:50 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration