DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 11, 2020

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Sent via email to: jczaban@loeb.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA take the following three actions described below:

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.

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.

Your submission was received by this office on 12/10/2020 and it was assigned docket number FDA-2020-P-2289. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.12.11 13:42:37 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)