FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

December 5, 2022

James N. Czaban
[redacted]

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

Dear Petitioner:

This letter responds to your citizen petition filed with the Food and Drug Administration (FDA) on December 11, 2020.

In your petition, you request that FDA "clarify and confirm circumstances, as described herein below, under which garments generically known as 'scrubs,' which are worn as daily-wear uniforms by a wide variety of employees in various healthcare settings, are not 'devices' within the meaning of the Federal Food, Drug and Cosmetic Act ("FDCA" or the "Act") and FDA's implementing regulations, and that such products also are not devices if they incorporate an antimicrobial component solely for purposes of protecting the garment."[1]

In responding to this petition, FDA reviewed the petition, the facts presented, and the comments received to the docket (FDA-2020-P-2289-0001).

In accordance with 21 CFR § 10.30(e), and for the reasons described below, we are denying your Petition.

I. Request for Action

In your petition, you request that 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:

[1]Citizen Petition, Consolidated Citizen Petition and Request for Advisory Opinion, Confirmation of Non-Device Status of Daily-Wear Uniform Scrubs and Antimicrobial Daily-Wear Uniform Scrubs, Docket Number FDA-2020-P-2289-0001, (hereinafter "Petition"), at 1.

- 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.

II. FDA's Regulation of Gowns and Other Apparel

Broadly, gowns and other apparel would be regulated as a device under Section 201(h) of the FDCA when they are intended for use in the diagnosis of disease or other conditions, or in the

cure, mitigation, treatment, or prevention of disease or when they are intended to affect the structure or any function of the body. On June 24, 1988, FDA issued a final rule identifying surgical apparel as "devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material." This rule further classified surgical gowns and masks as Class II devices and surgical apparel other than surgical gowns and masks as Class I devices.[2] On January 14, 2000, FDA issued a final rule to designate as exempt from premarket notification (510(k)) requirements surgical apparel other than surgical gowns and surgical masks, subject to the limitations of exemptions under 21 CFR 878.9.[3] FDA's interpretation of statutory and regulatory requirements that apply to Gowns and Other Apparel is further described in guidance.[4]

III. Discussion

(1) Response to Requested Action 1: Daily Wear Uniform Scrubs

In your first requested action you request, "FDA should issue a new or amended regulation, Guidance document, and/or an Advisory Opinion … and specifically clarify that the mere fact that a garment is 'intended for use by healthcare professionals' or for use in a 'healthcare facility or environment,' are not and will not form the bases for any FDA regulatory classification or enforcement action with respect to Daily-Wear Uniform Scrubs."[5] In arguing that FDA should issue a new or amended regulation, guidance document, and/or an advisory opinion you assert that recent FDA guidance documents have created confusion as to the regulatory status of Daily-Wear Uniform Scrubs.[6] However the guidance[7] you cite as support for this assertion, only emphasizes that "gowns and other apparel are devices when they meet the definition of a device set forth in section 201(h) of the FD&C Act."[8] The same guidance then provides factors FDA will consider when evaluating whether a gown and/or other apparel would be a medical device. Under section 201(h) of the FD&C Act, these products are devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease or when they are intended to affect the structure or any function of the body. FDA's regulations specify that the term "intended use" or similar words "refer[s] to the

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[2] See 53 FR 23874(June 24, 1988) and 21 CFR 878.4040, noting "Surgical suits and dresses, commonly known as scrub suits, are excluded."
[3] See 65 FR 2318 (January 14, 2000) and 21 CFR 878.4040.
[4] Guidance on Premarket Notification [510(k)] submissions for Surgical Gowns and Drapes. August 1993. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-premarket-notification-510k-submissions-surgical-gowns-and-surgical-drapes, Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings. December 2015. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings, and
Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. March 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health
[5] Petition at 7.
[6] Petition at 4.
[7] See Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. March 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.
[8] See Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. March 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.

objective intent of the persons legally responsible for the labeling of an article (or their representatives)."[9] 21 CFR 801.4 states that: "the intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article."[10] Consistent with FDA's regulations, the "considerations" listed in FDA's guidance document[11] are used to determine the objective intent of the manufacturer (i.e., intended use). Ultimately, whether a particular gown or other apparel meets the definition of a device in 201(h) will depend on its intended use. Because intended use decisions are product specific, FDA also provides advice to individual manufacturers based on their specific products, and it may be more helpful for manufacturers to seek our feedback through the options discussed below in section 3. If there is any regulatory uncertainty regarding a specific product and its intended use, FDA encourages sponsors to seek our feedback through one of these options.

(2) Response to Requested Action 2: Antimicrobial Daily Wear Uniform Scrubs

In your second requested action you request, "FDA should issue a new or amended regulation, guidance document, and/or an advisory opinion … and specifically clarify that the use of an EPA-registered antimicrobial agent in a Daily-Wear Uniform Scrub garment will not form the basis for any FDA regulatory classification or enforcement action."[12] You argue that the addition of an antimicrobial agent to non-FDA regulated products would not be sufficient to confer FDA jurisdiction over such products as devices. Additionally, you assert that Daily-Wear Uniform Scrubs with an added antimicrobial agent should not be regulated by FDA "if the intended use and claims for an antimicrobial component of a product are focused on the product itself and not on any disease- or health-related intended use." You also state, "if the intended use and claims for an antimicrobial component of a product are focused on the product itself and not on any disease- or health-related intended use, the product will not meet the definition of a device (or a drug) merely by reason of the addition of the antimicrobial component."[13] In arguing why you believe the Agency should clarify its position on the use of antimicrobial agents in Daily-Wear Uniform Scrubs, you cite statements in the Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings" (December 2015) ("2015 Gowns Guidance"), the Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency (March 2020) ("COVID-19 Gowns Guidance"), and the characteristics of devices that fall under product code QBW.

FDA agrees the addition of an antimicrobial agent to a product not otherwise regulated by FDA would not *solely* form the basis to confer FDA jurisdiction over such a product. None of the guidance documents you cite suggest otherwise. The COVID-19 Gowns Guidance merely notes that the presence of an antimicrobial agent would be a factor to consider in determining whether gowns or other apparel meet the definition of a device. [14] As you acknowledge, the 2015 Gowns

[9] See 21 CFR 801.4
[10] See 21 CFR 801.4
[11] See Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. March 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.
[12] Petition at 11.
[13] Petition at 8.
[14] See Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. March 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health

Guidance does not state that the addition of an antimicrobial agent to a gown or other apparel not otherwise regulated by FDA would solely form the basis to confer jurisdiction. Rather it indicates that manufacturers should utilize the pre-submission program as an option to obtain feedback on the data necessary to support claims associated with the addition of an antimicrobial agent.[15] Nor is a claim related to an antimicrobial agent alone solely determinative of whether a product is a device.[16] Instead, as mentioned above, whether a product is a device within the meaning of section 201(h) of the FD&C Act depends on its intended use. In determining the intended use of a product, FDA considers any relevant evidence, including statements and circumstances surrounding the manufacture and distribution of a product, among other evidence.[17] For example, the Agency may consider statements made by the manufacturer on the product's label, accompanying labeling, promotional statements, and advertising, among other sources.[18] FDA may also find it relevant to consider how the manufacturer has modified its statements over time and what consumers understand about changes to the manufacturer's claims. As discussed above intended use decisions are product specific and FDA provides advice to individual manufacturers based on their specific products, and it may be more helpful for manufacturers to seek our feedback through the options discussed below in section 3. If there is any regulatory uncertainty regarding a specific product and its intended use, FDA encourages sponsors to seek our feedback through one of these options. Finally, FDA agrees that the product code QBW does not form the "basis for FDA regulation of antimicrobial Daily-Wear Uniform Scrubs as 'devices.'"[19] The FD&C Act is the basis for regulating such devices. Classification product codes or product codes are instead "a method of internally classifying and tracking medical devices."[20]

(3) Conclusion of Response to Requested Actions 1 and 2

FDA assessed your requests for rulemaking, guidance, or advisory opinion in light of its other options and resource constraints. FDA operates with limited resources, and it evaluates options in terms of the extent of a potential risk, the time and delay that would accompany these actions, and the availability of other means to address concerns. Based on the aforementioned reasons FDA does not believe additional rulemaking, guidance, or an advisory opinion is warranted in response to the issues you raise regarding your first or second requested actions. FDA realizes manufacturers may have product specific questions as to whether their product meets the device definition, and the Agency provides several options for manufacturers to receive feedback from FDA including the Device Determination mailbox at DeviceDetermination@fda.hhs.gov and Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act.[21] For

[15] See Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings, December 2015, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings.

[16] See Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. March 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.

[17] See 21 CFR 801.4 and 21 CFR 201.128.

[18] See 21 CFR 801.4 and 21 CFR 201.128.

[19] Petition at 11.

[20] See Medical Device Classification Product Codes. April 2013. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff.

[21] See FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act. December 2019. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic.

the reasons detailed above FDA is denying your request for actions 1 and 2.

(4) Response to Requested Action 3: Enforcement Action

Finally, you request 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.[22]

This final requested action is not within scope of FDA's citizen petition procedures because it asks the Agency to refrain from taking enforcement action.[23] FDA has interpreted 21 CFR 10.30(k) as covering not only situations where enforcement action is requested, but also where the agency is asked to refrain from taking enforcement action. Consequently, FDA denies your request to refrain from any potential enforcement action and refers to the sections above for the Agency's explanation of its regulatory jurisdiction.

V. Conclusion

FDA has reviewed your petition along with other relevant information available to the Agency. For the reasons discussed above, the requests in your petition are denied.

If you have any questions in this regard, please contact Andrew Yeatts, Ph.D., by e-mail at Andrew.yeatts@fda.hhs.gov or at 301-796-4539.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
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[22] Petition at 2.
[23] See 21 CFR 10.30(k).