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Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, rm. 1061
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CONSOLIDATED CITIZEN PETITION AND REQUEST FOR ADVISORY OPINION
CONFIRMATION OF NON-DEVICE STATUS OF DAILY-WEAR UNIFORM SCRUBS AND ANTIMICROBIAL DAILY-WEAR UNIFORM SCRUBS

Petitioner, an apparel manufacturer, by its undersigned counsel and pursuant to 21 C.F.R. §§ 10.20, 10.30 (Citizen Petitions), and/or 10.85 (Advisory Opinions), requests that the Food and Drug Administration (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.

ACTIONS REQUESTED; ISSUES INVOLVED

Petitioner requests that the Commissioner 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.

Petitioner further requests 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.

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STATEMENT OF GROUNDS; STATEMENT OF FACTS AND LAW

I. REQUESTED ACTION NO. 1

A. Background; Daily-Wear Uniform Scrubs

In the modern U.S. healthcare setting, scrubs serve as the standard daily wear uniform for millions of nurses, healthcare technicians, other staff employees, and physicians. Typically, a hospital or hospital system will assign different color scrubs for different job functions (e.g., nurse vs technician vs physician, etc.) so that patients and other employees can identify a person's role and job function by the scrub color. In other healthcare settings, such as freestanding medical practices, healthcare workers have flexibility to choose scrubs with unique colors, patterns and designs of their choosing. In the case of nurses, scrubs have mostly replaced the traditional nurse's uniform of a white dress, apron, and cap as seen in vintage movies and television shows.[1]

The market for Daily-Wear Uniform Scrubs is huge, with at least one business magazine estimating a U.S. market size of $10 billion.[2] Daily-Wear Uniform Scrubs are sold via every common channel of trade, including by online scrub-specific specialty companies, mass-market online shopping sites such as Amazon.com, major discount retailers such as Wal-Mart, and specialty fashion brands such as Land's End.[3] Many nurses and other healthcare professionals are expected to purchase their own Daily-Wear Uniform Scrubs from a source of their choosing and with limited or no specific parameters set by their employer.

B. Daily-Wear Uniform Scrubs Are Not Medical Devices

Neither today's Daily-Wear Uniform Scrubs, nor the traditional nurse uniforms of yesteryear, are intended for any specific medical purpose that would render them "devices" under the FDCA. This is in contrast to surgical gowns and other surgical apparel which are designed and intended for specific medical purposes, and which are regulated by FDA under 21 C.F.R. § 878.4040. That surgical apparel regulation defines the relevant regulated articles as follows:

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[1] See e.g., https://work.chron.com/professional-attire-nurses-7735.html

[2] See https://www.inc.com/magazine/201809/lindsay-blakely/2018-inc5000-figs.html.

[3] See, e.g.,

https://www.scrubsandbeyond.com/all-outlet.html,

https://www.amazon.com/Medical-Uniforms-Scrubs/b?ie=UTF8&node=1268047011,

https://www.walmart.com/search/?query=scrubs,

https://business.landsend.com/search?q=scrubs

> *Surgical apparel are 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. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.*

21 C.F.R. § 878.4040(a) (emphasis added). Within this regulatory category, "surgical gowns" and "surgical masks" are regulated as Class II (Special Controls) devices, and "surgical apparel other than surgical gowns and surgical masks" are regulated as Class I (General Controls) devices. *Id.*

As emphasized above, the Surgical Apparel regulation states that "Surgical suits and dresses, commonly known as scrub suits, are excluded," from the scope of this regulatory category. That statement should, on its own, be sufficient to address this Petition's Request No. 1 in the affirmative – specifically, that Daily-Wear Uniform Scrubs are neither devices nor any other category of FDA-regulated article. Unfortunately, however, recent FDA statements have cast a cloud of ambiguity over this question, which has prompted Petitioner to seek the regulatory clarity requested via this Petition.

Specifically, in its Guidance, *Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency* (March 2020) (the "COVID-19 Gowns Guidance")[4], FDA arguably appears to take a much broader view of the criteria by which certain apparel can be regulated as a device, *including by reason of the mere fact that such garments are intended for use by any healthcare professionals*. Among the confounding statements made in that Guidance, are the following:

- "Generally, gowns, other apparel, and gloves fall within this definition [of "device"] when they are intended for a medical purpose, including for use by health care professionals." (p.3);
- "When evaluating whether these products are intended for a medical purpose, among other considerations, FDA will consider whether:

  > "1) they are labeled or otherwise intended for use by a health care professional;
  >
  > "2) they are labeled or otherwise for use in a health care facility or environment; and

[4] Available at https://www.fda.gov/media/136540/download.

"3) they include any drugs, biologics, or anti-microbial/anti-viral agents." (p.5).

- "it is the current view of the Agency that a gown that is not intended for use as a "surgical gown" is a class I device…." (p.6)

Moreover, the COVID-19 Gowns Guidance contrasts what it appears to consider "medical purposes," namely use "by a health care professional" "in a health care facility or environment," with unduly narrow examples of "non-medical" purposes, specifically "construction and other industrial applications," and "manufacturing or research and development."[5]

These statements, on their face, have raised the concern that FDA may be seeking to expand its regulatory reach beyond the natural and logical scope of the FDCA's device definition and beyond the scope of the agency's own regulations, in order to seek to classify Daily-Wear Uniform Scrubs as devices. Petitioner prefers to believe, however, that such an interpretation would misconstrue the agency's intent and that those statements are merely confusingly-worded efforts to describe FDA's regulatory approach to articles of apparel that, *for other reasons*, may be within the scope of FDA's device regulatory jurisdiction.

For example, the Guidance uses inappropriately narrow comparisons between medical uses (healthcare professionals broadly; any healthcare facility or environment) and non-medical uses (construction, industrial, R&D, manufacturing). In fact, a wide variety of uses of Daily-Wear Uniform Scrubs by healthcare professionals in a healthcare facility or environment must be considered "non-medical" uses given that the Guidance is based on FDA's existing Surgical Apparel regulation, which only applies a device classification to garments "that are intended to be worn by operating room personnel during surgical procedures."[6] In other words, "medical uses" is the narrower category under the regulation, whereas "non-medical uses" is the much broader category. *FDA's Guidance statements get this distinction exactly backwards.*

More specifically with respect to the meaning of "medical uses" under the regulation and Guidance, relevant products regulated as devices within the meaning of 21 C.F.R. § 878.4040 and the Guidance are limited to surgical-setting "Gowns and other apparel [that] are products intended to protect the wearer from the transfer of materials in the wearer's environment."[7] Daily-Wear Uniform Scrubs are not intended to "protect" the wearer from "materials" in a healthcare setting any more than a traditional nurse's uniform would. And, Daily-Wear Uniform Scrubs would be no more "protective" than normal street clothes, which such scrubs in fact replace as a workplace uniform. By way of analogy, nurses in particular desire specialized shoes for work, given the grueling and specialized demands of the job, and internet searches for "best

[5] COVID-19 Gowns Guidance at 5.

[6] 21 C.F.R. § 878.4040(a) (emphasis added).

[7] COVID-19 Gowns Guidance at 2.

shoes for nurses" generates thousands of results for shoes specifically designed and intended for use by nurses.[8] It would, of course, be absurd for FDA to regulate such shoes as devices merely based on the fact that they are "intended…for use by health care professionals" such as nurses. It is equally absurd for FDA to seek to regulate Daily-Wear Uniform Scrubs merely because those garments are intended for use by medical professionals.

Adding to the confusion generated by FDA's COVID-19 Gowns Guidance, only if a scrub were to be sold with specific claims about "barrier protection" or protection against infection or contamination from a patient's bodily fluids would the product be subject to FDA regulation under 21 C.F.R. § 878.4040, and the prior FDA Guidance, *Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings* (Dec. 9, 2015) (the "2015 Gowns Guidance").[9] That Guidance explained the bases for FDA's regulation of "surgical apparel," with classification as either Class II or Class I dependent on the type of barrier protection claims made for the garment at issue (based on ANSI/AAMI/PB70 performance level definitions). The types of Daily-Wear Uniform Scrubs at issue in this petition do not make any such barrier protection claims and cannot, therefore be regulated as "surgical apparel" devices.

Finally, FDA's surgical apparel regulation, and the preamble to the final rule establishing that regulation, further support the non-regulation of Daily-Wear Uniform Scrubs. Specifically, 21 C.F.R. § 878.4040(a) excludes FDA regulation of "Surgical suits and dresses, commonly known as scrub suits." The 1988 Final Rule preamble explains this exclusion as follows:

> Comments stated that surgical suits and dresses, commonly known as scrub suits, are intended to replace the street clothes of operating room personnel, but are not intended to be part of the sterile field. The comments said that surgical gowns that are intended to be part of the sterile field are worn over scrub suits to protect the wearer and the patient from bacterial contamination. The comments questioned including scrub suits as a category of medical devices….[10]

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[8] See e.g., Bing search: https://www.bing.com/search?q=best%20shoes%20for%20nurses&qs=n&form=QBRE&msbsrank=6_6__0&sp=-1&pq=best%20shoes%20for%20nurse&sc=6-20&sk=&cvid=2402E8A27C2141F6A4886847F6C45639;

See also Google search: https://www.google.com/search?source=hp&ei=NlnOX4r7CY6D9PwPhuGr6A4&q=best+shoes+for+nurses&oq=best+shoes+for+nurses&gs_lcp=CgZwc3ktYWIQAzIFCAAQyQMyAggAMgIIADICCAAyAggAMgIIADICCAA6CwguELEDEIMBEJMCOg4ILhCxAxCDARDHARCjAjoICC4QsQMQgwE6CwguELEDEMcBEKMCOggIABCxAxCDAToICC4QxwEQowI6AgguOhEILhCxAxCDARDHARCjAhCTAjoFCAAQsQM6CAgAELEDEMkDULsJWI8jYJEkaABwAHgAgAF8iAGEC5IBBDIwLjGYAQCgAQGqAQdnd3Mtd2l6&sclient=psy-ab&ved=0ahUKEwiK7oqGprztAhWOAZ0JHYbwCu0Q4dUDCAk&uact=5

[9] Available at https://www.fda.gov/media/92146/download.

[10] 53 Fed. Reg. 23856, 23863 (June 24, 1988) (emphasis added).

The agency accepted those comments, explaining that "FDA agrees with the comments that questioned the inclusion of scrub suits as medical devices. FDA has decided not to classify surgical suits and dresses, commonly known as scrub suits, as medical devices. FDA is changing the identification of surgical apparel to exclude surgical suits and dresses."[11]

C. Conclusion: Requested Action No. 1

For the foregoing reasons, Daily-Wear Uniform Scrubs as described herein are not and cannot properly be regulated by the FDA. FDA should issue a new or amended regulation, Guidance document, and/or an Advisory Opinion to that effect, 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.

II. REQUESTED ACTION NO. 2

As is very common in the apparel industry, Petitioner offers many products that are treated with EPA-registered antimicrobial agents for the intended purposes of reducing odor, protecting the fabric from stains and degradation, and extending the life of the garment. Indeed, internet searches reveal the ubiquity of such products in the market.[12]

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[11] Id. at 23863-23864 (emphasis added).

[12] See e.g.:

- Google search for "antimicrobial underwear": https://www.google.com/search?q=antimicrobial+underwear&source=lnms&sa=X&ved=0ahUKEwjW5fWos7ztAhXGAp0JHbvuCxMQ_AUI_AYoAA&biw=2560&bih=899.
- Google search for "antimicrobial workout clothes": https://www.google.com/search?biw=2560&bih=899&ei=TGjOX5_oB8ePtAa5jZK4CA&q=antimicrobial+workout+clothes&oq=antimicrobial+workout+clothes&gs_lcp=CgZwc3ktYWIQAzIFCAAQyQM6BAgAEEc6BwgAEMkDEEM6AggAOgQIABBDOgYIABAWEB5QzVNYnWBgsmFoAHACeACAAWCIAe4EkgEBOJgBAKABAaoBB2d3cy13aXrIAQjAAQE&sclient=psy-ab&ved=0ahUKEwifvs63tLztAhXHB80KHbmGBIcQ4dUDCA0&uact=5
- Amazon.com Search for "antimicrobial socks": https://www.amazon.com/s?k=antimicrobial+socks&ref=nb_sb_noss_2
- Amazon.com search for "antimicrobial shirt": https://www.amazon.com/s?k=antimicrobial+shirt&ref=nb_sb_noss_2
- Amazon.com search for "antimicrobial underwear": https://www.amazon.com/s?k=antimicrobial+underwear&ref=nb_sb_noss_1.

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A. Antimicrobial Daily-Wear Uniform Scrubs are not Devices When the Antimicrobial is Intended Solely to Protect the Garment

The use of antimicrobial components in garments, including Daily-Wear Uniform Scrubs as described herein, is consistent with the Environmental Protection Agency's (EPA) "treated article exemption" regulation, 40 C.F.R. 152.25(a), and the EPA's Pesticide Registration (PR) Notice 2000 - 1*, "*Applicability of the Treated Articles Exemption to Antimicrobial Pesticides*" (the "Treated Articles Guidance"). [13] This Treated Articles Exemption policy permits the addition of an EPA-registered "antimicrobial" to products under certain conditions, without the need to comply with any otherwise-applicable regulatory requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). To summarize the scope of the Treated Articles Exemption, the Treated Articles Guidance states that "EPA considers terms such as "antimicrobial," "fungistatic," "mildew-resistant," and "preservative," as being acceptable for exempted treated articles or substances provided that they are properly, and very clearly, qualified as to their intended non-public health use."[14] Among the antimicrobial claims that EPA considers acceptable under the Treated Articles Exemption are claims for:

- Protecting the product from deterioration,
- Extending the useful life of a product,
- Preventing discoloration,
- Resisting stains, and
- Resisting and mitigating odors on the product.

The principal limitation to the Treated Articles Exemption is that "public health" claims, such as claims that the component will kill bacteria, provide a germ-resistant surface, or reduce cross-contamination, should not be made.[15] These operative elements of the Treated Articles Exemption conceptually parallel the statutory criteria required to be used by FDA to classify a product as a device or a "drug" under 21 U.S.C. § 321(h) or 321(g). Under those definitions, in order to be regulated as a device, a product must be intended to diagnose, cure, mitigate, treat or prevent a disease or other medical condition. Thus, 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. Accordingly, the addition of an

[13] Available at https://www.epa.gov/pesticide-registration/prn-2000-1-applicability-treated-articles-exemption-antimicrobial-pesticides.

[14] Treated Articles Guidance at 3 (emphasis added).

[15] Treated Articles Guidance at 5.

antimicrobial ingredient to otherwise non-FDA-regulated products, such as socks, underwear, t-shirts, and Daily-Wear Uniform Scrubs, does not confer jurisdiction to the FDA to regulate such products as "devices."[16]

B. FDA's Regulations and Guidances do not Confer Authority to Regulate Daily-Wear Uniform Scrubs as Devices Merely Based on Inclusion of an Antimicrobial Component

It is a straightforward conclusion that an otherwise non-FDA-regulated article of clothing, including Daily-Wear Uniform Scrubs, does not become an FDA-regulated device due to the addition of an antimicrobial component with intended uses and claims limited to protecting the garment itself (from stains, odors, discoloration, or premature degradation, etc.). Nevertheless, certain statements in FDA's recent Guidances have the potential to cause, and have caused, confusion and uncertainty as to FDA's intent and/or claimed authority with respect to such products. This Petition requests that FDA clarify its position on these matters, including with respect to the following statements in existing FDA regulatory documents.

1. The 2015 Gowns Guidance

FDA's 2015 Gowns Guidance states that "this guidance does not address the data needed to support the addition of antimicrobial agents in gowns. Manufacturers desiring to market gowns with these types of claims and/or design features are encouraged to utilize the pre-submission process."[17] On its face, this statement suggests that FDA believes that any addition of an antimicrobial agent to a hospital garment in and of itself, does, or could, render the product a device.

However, not only would such an interpretation be at odds with the controlling statutory definition of "device" in the context of Daily-Wear Uniform Scrubs, the 2015 Gowns Guidance, when read in context, only applies "to gowns regulated under 21 CFR 878.4040. Specifically…gowns with claims that they meet certain liquid barrier performance standards established by the American National Standards Institute, Inc., and the Association for the Advancement of Medical Instrumentation (ANSI/AAMI) and other similar terminology associated with these claims."[18] Because Daily-Wear Uniform Scrubs are not regulated under section 878.4040, and do not make barrier protection claims, Petitioner seeks FDA confirmation and clarification that the 2015 Gowns Guidance does not permit or support FDA regulation of

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[16] To be clear, FDA does not have the regulatory authority to opine on whether a product does or does not comply with the EPA's regulations, including the Treated Articles Exemption, nor to enforce any EPA regulations. However, FDA should not assert regulatory interpretations nor take enforcement actions that conflict with established regulations of other federal agencies.

[17] 2015 Gowns Guidance at 7.

[18] Id. at 3 (emphasis added).

Antimicrobial Daily-Wear Uniform Scrubs merely due to the inclusion of antimicrobial components. Rather, such products must be deemed non-FDA-regulated products, just like other non-medical garments (t-shirts, socks, underwear, etc.) which are widely marketed with antimicrobial components designed exclusivity to protect the garment itself.

2. The COVID-19 Gowns Guidance

While the 2015 Gowns Guidance leaves no legitimate room for FDA to regulate appropriately-labeled Antimicrobial Daily-Wear Uniform Scrubs as devices, Petitioner is concerned that the COVID-19 Guidance may reflect an unannounced effort by FDA to lay the groundwork for a new regulatory policy that Antimicrobial Daily-Wear Uniform Scrubs could be regulated as devices based on a combination of their use by healthcare workers in a healthcare setting, plus the inclusion in the product of an "anti-microbial" component. Specifically, as discussed previously above, this Guidance states that

> When evaluating whether these products are intended for a medical purpose, among other considerations, FDA will consider whether:
>
> > 1) they are labeled or otherwise intended for use by a health care professional;
> >
> > 2) they are labeled or otherwise for use in a health care facility or environment; and
> >
> > 3) they include any drugs, biologics, or anti-microbial/anti-viral agents.

COVID-19 Gowns Guidance at 5 (emphasis added).

As discussed above, any attempt by the agency to equate the end-users and the use setting for Daily-Wear Uniform Scrubs (i.e., nurses, etc. in a hospital or other healthcare setting) with an intended use for "medical purposes" runs afoul of the statutory definition of "device" as well as the surgical-use limitations of the very regulation the Guidance purports to be explaining. The additional purported "medical use" criteria – the inclusion of an antimicrobial component – is similarly unavailing as a basis to assert regulatory jurisdiction over Daily-Wear Uniform Scrubs under the circumstances at issue in this Petition. In other words, when used as daily uniforms by non-surgical personnel or otherwise outside the surgical suite, Daily-Wear Uniform Scrubs are not "devices." As non-devices, these products may incorporate antimicrobial components for limited purposes of protecting the garment to the same extent as any other non-medical garment without thereby becoming FDA-regulated devices.

3. Surgical Apparel With Material Claims -- Product Code QBW

FDA's existing device Product Code for Surgical Apparel With Material Claims (Product Code QBW) does not change the foregoing analysis and conclusion that Antimicrobial Daily-Wear Uniform Scrubs are not and cannot be regulated as medical "devices" under the conditions specified in this Petition.

Product Code QBW is only operative pursuant to the surgical apparel regulation, 21 C.F.R. § 878.4040, and this Code applies to "Surgical apparel…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…." Such products may include apparel "constructed, treated, modified, and/or coated with substances that are intended or known to create or enhance a functional element of the device," in particular that the garment "contains specific materials that are intended to enhance inhibition of microorganism transfer, reduce soil retention, or kill microorganisms on the device surface or within the device material under specified contact conditions."[19]

None of the mandatory elements of Product Code QBW apply to Daily-Wear Uniform Scrubs, which are not within the scope of section 878.4040, are not worn by operating room personnel, are not worn during surgical procedures, and do not make claims to protect the wearer, patients, or any other person from the transfer of microorganisms or other potentially infectious material. Accordingly, this Product Code is inapplicable to Daily-Wear Uniform Scrubs and cannot be the basis for FDA regulation of antimicrobial Daily-Wear Uniform Scrubs as "devices."

C. Conclusion – Requested Action No. 2

For the reasons set forth in Sections I and II above, Daily-Wear Uniform Scrubs with an added antimicrobial component(s), the claims for which are limited to the protection or enhancement of the garment itself, are not, and cannot properly be, regulated by the FDA. FDA should issue a new or amended regulation, Guidance document, and/or an Advisory Opinion to that effect, 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.

III. REQUESTED ACTION NO. 3

Based on the foregoing facts, law, and analyses, Petitioner believes that each of Requested Action No. 1 and Requested Action No. 2 should, and indeed must, be granted by the Agency. Accordingly, Petitioner has a good faith belief that its commercialization of Daily-Wear Uniform

[19] See Product Code QBW, at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=2903.

Scrubs and Antimicrobial Daily-Wear Uniform Scrubs under the conditions described herein is not, and would not be, subject to FDA regulation. Petitioner therefore intends to engage in the commercialization of such products unless and until the FDA issues a definitive substantive response to this Petition fully explaining a contrary FDA position.[20]

Petitioner recognizes that FDA may not have specifically considered the ambiguity of, and confusion created by, certain statements made in recent Guidances (as discussed herein). Accordingly, in the event the agency makes a final determination that Daily-Wear Uniform Scrubs and/or Antimicrobial Daily-Wear Uniform Scrubs are in fact FDA-regulated devices and subject to specific FDA regulatory requirements, Petitioner requests that the FDA refrain from taking any action – including 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 or Antimicrobial Daily-Wear Uniform Scrubs, until at least 180 days after FDA:

- issues a complete substantive response denying the requests made herein,
- fully explains in such response the agency's legal bases for asserting regulatory jurisdiction over such products,
- publishes notice of such determination in the Federal Register, and
- specifically identifies such response as a "final agency action" within the meaning of the Administrative Procedure Act, 5 U.S.C. § 704.

ENVIRONMENTAL IMPACT

Petitioner claims a categorical exclusion under one or more provisions of 21 C.F.R. §§ 25.30-25.34.

ECONOMIC IMPACT

Petitioner will submit economic impact information upon the request of the Commissioner.

[20] Petitioner reserves its right, however, to seek judicial review of any such adverse FDA action or determination.

CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

James N. Czaban

Respectfully submitted,

James N. Czaban
Rachel A. Gartner
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