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Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Health Care Antiseptic Drug Products; Reopening of the Administrative Record; Docket No. 75N-183H

Dear Sir or Madam:

GOJO Industries, Inc. (GOJO) submits these comments to the above-referenced rulemaking. Since 1946, GOJO has been a leading supplier of hygiene and skin care products for retail, healthcare, manufacturing, education, foodservice, automotive, and other markets. GOJO's products include PURELL® Instant Hand Sanitizer, an alcohol-based instant hand sanitizer. These comments specifically address the application of the tentative final monograph (TFM) to instant hand sanitizers.

At the outset, however, GOJO wishes to state its strong support for the Healthcare Continuum Model (HCCM), which was submitted to the record in this proceeding by the Cosmetic, Toiletry and Fragrance Association and the Soap and Detergent Association. The HCCM proposes appropriate classifications for antimicrobial wash products, with accompanying labeling for each category that ensures safe and effective use by consumers and healthcare personnel. GOJO urges FDA to incorporate the HCCM into this monograph.

I. Background

On May 29, 2003, FDA published a proposed rule in the Federal Register announcing the reopening of the administrative record for the Topical Antimicrobial Drug Products for Over-the-Counter (OTC) Human Use with respect to health-care antiseptic drug products. 68 Fed. Reg. 32003 (May 29, 2003). The

Topical Antimicrobial Rulemaking was previously divided by the FDA into two separate rulemaking proceedings on the related categories of health care antiseptics and first aid antiseptic products. The May 29, 2003 Proposed Rule, to which these comments are directed, pertains specifically to the former, i.e., the amended TFM on health care antiseptic drug products that was published on June 17, 1994 (59 Fed. Reg. 31402).

The health care antiseptic TFM includes three categories of products: (1) Antiseptic Handwash or Healthcare Personnel Handwash products; (2) Patient Preoperative Skin Preparation products; and (3) Surgical Hand Scrub Products. In addition, FDA indicated in the TFM that it would also consider data submitted for products to be used in the food industry such as hand sanitizers or hand dips. 59 Fed. Reg. at 31440. These comments pertain to the first category of products--those that the FDA, in the proposed TFM published almost 10 years ago, called "Antiseptic Handwash or Healthcare Personnel Handwash" products.

Since before the publication of the TFM, GOJO and other companies have marketed alcohol-based, instant hand-sanitizer products, such as PURELL®, under the "healthcare antiseptic handwash" category in the TFM. As with many other similar products, PURELL® is labeled as an "instant hand sanitizer" and contains the active ingredient ethyl alcohol (62%). It is labeled for use in killing most common germs on the hands. PURELL® and similar products have achieved substantial consumer recognition and acceptance as "hand sanitizers." They are also now recommended by the CDC for several home hand hygiene and healthcare setting uses.[1] Indeed, the FDA itself recommends such products for "clean[ing] hands when water is not available...."[2]

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1 CDC's "Guideline for Hand Hygiene in Health-Care Settings;" published in Morbidity and Mortality Weekly Report; Vol 51, Oct. 25, 2002.

2 FDA/CFSAN Food Safety A to Z Reference Guide, September 2001, http://www.cfsan.fda.gov/~dms/qa-prp3.html. The full Question and Answer states: "**Q How can I clean my hands when water is not available, such as when traveling or picnicking away from home? A** You can use disposable wipes or a hand gel sanitizer. You use the gel without water. The alcohol in the gel kills the germs on your hands. You can find disposable wipes and hand gel sanitizers in most supermarkets and drugstores."

GOJO is submitting these comments to highlight a number of points relating to use of hand sanitizers that have arisen since the publication of the TFM which FDA should consider and incorporate into the final monograph for these products. They primarily address the goal of providing appropriate labeling and claims for consumer use of these products outside of the professional healthcare setting. In addition, FDA's new Drug Facts labeling requirement applicable to all OTC drugs creates the need for a number of changes to the monograph language from that proposed in the TFM. These issues are described below.

II. The Final Monograph Should Adopt A More Appropriate Statement Of Identity For The Product.

A. These Products Are Commonly Known As "Instant Hand Sanitizers" And Should Be Labeled As Such.

As with all OTC drug monographs, the TFM requires each drug product's "statement of identity" to be prominently featured on the principal display panel of an OTC drug. See, e.g., 21 C.F.R. § 333.455. The statement of identity is required by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(c)(1)(A)(i), and the Fair Packaging and Labeling Act, 15 U.S.C. § 1453(a)(1). FDA's general OTC drug labeling regulations require that the statement of identity include "the established name of the drug, if any there be, followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug." 21 C.F.R. § 201.61(b). Furthermore, in the context of a mixture without an established name, FDA specifies that the general pharmacological action or principal intended action shall be "in terms that are meaningful to the layman." Id.

The statement of identity proposed for these instant hand sanitizer products in the TFM is: "'antiseptic,' . . . and/or 'antiseptic handwash' or 'healthcare personnel handwash.'" 21 C.F.R. § 333.455(a). As described below, however, limiting the statement of identity on the principal display panel to one or more of these phrases would inadequately identify the product and create consumer confusion. Through more than two decades of use, these products have become known and established in the marketplace as "hand sanitizers." They are not, generally, labeled as antiseptics or antiseptic handwashes,

or as healthcare personnel handwashes. Indeed, as noted above, the FDA's own food safety reference guide refers to these products as "hand sanitizer gels."[3]

The phrase "handwash" is misleading as applied to many of these products; in common usage and understanding, "wash" refers to a product applied and used with water or with soap and water to wash the hands. That is to be contrasted with lotion or gel products, such as PURELL® , that are simply rubbed into the skin and then allowed to dry. Therefore, FDA should include other terms, such as "hand sanitizer" or "instant hand sanitizer" rather than the terms proposed in the TFM for the statement of identity. PURELL® and similar products have been labeled, advertised and sold as "instant hand sanitizers" for decades. That is the terminology consumers and health care workers know, understand and recognize. It is also the term used in the industry.

Indeed, in addition to the examples cited above where FDA has recognized and referred to these products as hand sanitizing gels, the Centers for Disease Control and Prevention (CDC) also refers to these products in terms that reflect the common usage and understanding, such as "hand sanitizers" and "hand rubs." For example, the CDC recently issued guidance for the airline industry on proper handling of passengers suspected of having severe acute respiratory syndrome (SARS). The guidance advises employees that "[h]ands should be washed with soap and water or an alcohol-based *hand sanitizer* immediately after gloves are removed."[4] (Emphasis added.) Both consumers and experts in contagious diseases thus now commonly use the phrase "hand sanitizer" to describe this class of products.

B. The Reference To "Antiseptic" In The Statement Of Identity Is Confusing And Should Be Deleted Or Made Optional.

In addition to using the term hand sanitizer to describe the product, we respectfully submit that the FDA should also amend the monograph to remove the proposed requirement that hand sanitizers (perhaps other than "healthcare personnel handwashes) be labeled as "antiseptics." While the phrase "hand sanitizer," or "instant hand sanitizer," by itself, is sufficient to communicate to consumers the nature and

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[3] See note 2, supra.

[4] Interim Guidance for Cleaning of Commercial Passenger Aircraft (May 8, 2003), available at: http://www.cdc.gov/ncidod/sars/aircraftcleanup.htm.

appropriate use of these products, the TFM would require inclusion of the term "antiseptic" as part of the full statement of identity for these products.[5] GOJO submits that, given the common usage and consumer understanding of the term antiseptic, its use in this context is at best confusing and, at worst misleading to consumers.

Specifically, it appears that consumers generally regard the term "antiseptic" as referring either to a first aid product, intended for use on minor cuts, scrapes or burns, or as a mouthwash intended to "kill germs that cause bad breath." To our knowledge, consumers do not perceive instant hand sanitizers as being "antiseptics" in this common sense, even though they expect these products to kill germs on the hands.[6] Indeed, using the word "antiseptic" on a hand sanitizer product might mislead consumers into using the product improperly as a first aid medicament. Thus GOJO urges the FDA to eliminate or make optional inclusion in the statement of identity the word "antiseptic." The appropriate statement of identity for the product should be, simply, "hand sanitizer" or "instant hand sanitizer". Manufacturers should have the option to add other truthful, nonmisleading terms, such as antimicrobial or antibacterial, at their discretion.

III. Issues Relating To The New Drug Facts Labeling Requirements.

A. The Proposed "Indications" Section Contains Three Specific Examples Of Appropriate Situations For Use Of Hand Sanitizer Products; Manufacturers Should Not Be Limited To The Specific, Situational Examples Proposed In The TFM.

As proposed, the § 333.455 (b) states:

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[5] It is instructive that the TFM would exclude the word antiseptic from "healthcare personnel handwashes," which can be identified with that phrase alone. This suggests that healthcare personnel understand the use of such products. The same conclusion should apply to consumers.

[6] A search for the term "antiseptic" on the www.drugstore.com web site yielded 38 products, primarily first aid (wound) products and oral care/mouthwash products. No products in the hand sanitizer category were returned, although one surgical hand scrub/patient pre-op product was included. In contrast, a search for "hand sanitizer" yielded 69 "hits," including mostly hand sanitizers and antibacterial/antimicrobial soaps. Similar results were obtained by searching www.CVS.com.

III. Issues Relating To The New Drug Facts Labeling Requirements.

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As proposed, the § 333.455 (b) states:

> The labeling of the product states, under the heading "indications," any of the phrases listed in this paragraph that are applicable to the product. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used...

That is followed by proposed § 333.455(b)(2), which would establish the following indications for the "handwash" category:

> "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.")

These proposed indications include three precisely defined examples of the situations where use of these products is appropriate.

Under the FDA's flexibility policy, a manufacturer is permitted to use truthful, non-misleading synonyms for the indications for use, but must use exact monograph language, (where the monograph language is in quotation marks) for other mandatory aspects of labeling . See 21 C.F.R. 330.1(c)(2). Here, the FDA should confirm that this truthful, non-misleading synonym policy extends to the specific situational examples noted in the proposed indications, such that inclusion of other appropriate, truthful situational options, would be permitted in addition to, or in lieu of, the three options contained in the TFM. For example, manufacturers should also be able to state that the products could be used for hand sanitizing to kill germs on the skin "before or after eating," "after smoking," "before handling food", or "in situations where soap and water are unavailable." FDA should clarify in the final monograph that examples of other similar uses in settings outside of healthcare are permitted in the indications section of the label.

statement. Bacteria is included in the category of microorganisms that consumers commonly refer to as "germs;" moreover, consumers are more likely to understand that germs (as opposed to "bacteria") have a role in potentially causing disease. In that connection, FDA acknowledges that these terms are comparable by noting in the preamble to the TFM that it had no objection to use of either "germicide" or "microbicidal" for professional use products in the same category. 59 Fed. Reg. at 31425.

GOJO believes that phrases such as "to decrease germs on the skin" communicate in simple terms the indicated use of these products. They should be specifically authorized in the final monograph to ensure that this category of products continues to be understood by, and useful to, consumers. To that end, the final monograph should specifically authorize the use of the indication: "Kills 99.99% of most common germs that may cause illness (or cause disease) (or make you sick)," or "Kills germs that can cause illness (or cause disease) (or make you sick)," if such claim is substantiated by the monograph-specified test methods.

C. The Directions For Use Should Be Modified To Fit Other Dosage Forms That Are Authorized And Should Be Simplified To Eliminate The References To Grams.

Hand sanitizers have been marketed and have attained broad consumer acceptance in a number of different dosage forms, including gels/lotions/rubs, and wipes. The TFM did not propose to limit the dosage forms of these products.[7] We agree with the Agency's position on dosage forms as stated in the TFM. The surface areas of hands vary by individual; a child's hand is significantly smaller than an adult. In addition circumstances for the use of these products vary. Healthcare workers or food handlers need to sanitize not only their hands but their wrists and forearms. Consumers may need only to sanitize their hands.

The TFM proposes two sets of directions for use in the "health care personnel handwash" (hand sanitizer) category. The first set, in proposed § 333.455(c)(1), is for products to be used with water, and is clearly designed and intended for institutional healthcare worker settings. The second set of directions, in

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[7] According to the preamble to the TFM, "specific dosage forms are not being included in the monograph unless there is a particular safety or efficacy reason for doing so. Antimicrobial ingredients may be formulated as soaps for some of the uses discussed in this document, e.g., handwash...." 59 Fed. Reg. at 31407.

circumstances for the use of these products vary. Healthcare workers or food handlers need to sanitize not only their hands but their wrists and forearms. Consumers may need only to sanitize their hands.

The TFM proposes two sets of directions for use in the "health care personnel handwash" (hand sanitizer) category. The first set, in proposed § 333.455(c)(1), is for products to be used with water, and is clearly designed and intended for institutional healthcare worker settings. The second set of directions, in § 333.455(c)(2), is more appropriate for general consumer hand sanitizers. It offers a long and a short option:

> (c)(2) For products to be used without water: "Place a 'palmful' (5 grams) of product in one hand. Spread on both hands and rub into skin until dry (approximately 1-2 minutes) Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds)" or "Wet hands thoroughly with product and allow to dry without wiping."

GOJO believes that these directions could be simplified and improved to be more user-friendly. For example, for a product which is used without water, we would propose the following simple alternative language:

> Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry.

These concise, direct instructions provide synonymous information to the TFM's proposed language, but without the complicating verbiage about the quantity of the product and length of use. Since the majority of hand sanitizers are formulated with alcohol which evaporates rapidly, providing time-based use instructions is not necessary.

Similarly, the FDA should permit consumer-friendly language for hand-sanitizer products in other commonly marketed dosage forms, such as wipes. For example, the directions could state:

> Moisten hands thoroughly with wipe and allow hands to dry.

Such simple directions should be included in the final monograph in addition to the more technical healthcare worker directions to encourage safe and convenient home use of hand sanitizer products.

D. FDA Should Waive The Required Warning To "Keep Out Of Reach Of Children" For Instant Hand Sanitizers.

GOJO urges the FDA to waive the requirement for the standard "keep out of reach of children" warning required under 21 C.F.R. § 330.1(g). Because these hand sanitizer products are intended for use by both adults and children in a variety of settings, including homes or classrooms, zoos, amusement parks, retail food service establishments and elsewhere, GOJO believes the standard warning will lead to consumer confusion over the appropriateness of the use of these products by children. Moreover, this confusion will be magnified by FDA's new Drug Facts labeling format, which will increase prominence and comprehension of warnings and will place them in closer proximity to the directions for use.

This problem is worsened by the fact that several states prohibit the use in nursing homes of products that are labeled "keep out of reach of children". Some state health inspectors have concluded that such a warning indicates a patient with dementia may be at risk from exposure to such products labeled in this way. This prevents the lawful use of these products by or for a large number of patients who can most benefit from their availability. Healthcare workers in nursing home settings are then limited to the availability of the product because it cannot be kept in close proximity to the patients.

Consumers can also be confused by the stand-alone statement "keep out of reach of children" for it implies to the consumer that products carrying this warning are never to be used by children.

Under these circumstances, FDA should waive the requirement for the standard "keep out of reach of children" warning, as permitted by § 330.1(g), and create suitable substitute language in the final monograph that is consistent with the use of these products by children. For example, an alternative warning might state: "Children under 6 years of age should be supervised when using this product." Such a warning is more consistent with the marketed use of the product, and will tend to minimize consumer confusion or the possible perception that a product marketed for use by children is somehow unacceptably dangerous.

A similar approach was taken in the final anticaries monograph for fluoride dentifrices. The warning states: "Keep out of reach of children under 6 years of age." 21 C.F.R. § 355.50(c)(1). Directions for the products state, in pertinent part: "Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision." Id. at § 355.50(d)(1).

For the instant hand sanitizers, GOJO believes it is most appropriate to require a concise warning or directions of this type. Anything more hinders the safe and effective use of these products.

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In closing, GOJO welcomes the opportunity to comment on this increasingly important category of products. For the reasons stated above, GOJO urges the FDA to adopt appropriate language in the monograph to meet current consumer understanding and use of the hand sanitizer category, in finalizing the appropriate monograph conditions, and in particular, the appropriate labeling, for this product category.

Sincerely,

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