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Food & Drug Administration
Department of Health & Human Services
Room 1-23,
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Rockville, MD 20857

cc Dr. Ganley & Ms. Lumpkins

**Citizen Petition to Amend the OTC Labeling in the Tentative Final
Monograph for Health-Care Antiseptic Drug Products: Docket 75N-183H**

The undersigned submits this petition under 21 CFR § 10.30 of the Federal Food, Drug & Cosmetic Act to request the Commissioner of Food & Drugs to take the following actions on proposed 21 CFR Part 333, the OTC Tentative Final Monograph for Health-Care Antiseptic Drug Products:

- to include appropriate OTC labeling for product categories in the Health Care Continuum Model into the Monograph;
- to modify the "Keep out of reach of children statement" for consumer hand and consumer body product categories in the Health Care Continuum Model;
- to provide reduced content and format alternatives for small packages of topical antibacterial products in the Monograph.

ACTION REQUESTED

The Petitioner requests that the Commissioner consider this petition to amend proposed 21 CFR 333, the June 17, 1994 Tentative Final Monograph for Health-Care Antiseptic Drug Products Proposed Rule [59 FR 31401] as follows:

- amend § 333.450, § 333.455, § 333.460, and § 333.465 to include appropriate labeling for health-care antiseptic drug products including surgical hand scrub, patient pre-operative skin preparation and health-care personnel hand products in the Monograph, as described in Attachment 1, Tables 1-3;
- amend 21 CFR 333 to include labeling in the Monograph for the remaining topical antibacterial product categories which comprise the Health-Care Continuum Model, specifically food handler, consumer hand and consumer body OTC drug products, as described in Attachment 1, Tables 4-6;

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CTFA is the national trade association representing the cosmetic, toiletry and fragrance industry. Founded in 1894, CTFA has an active membership of approximately 300 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States. CTFA also includes approximately 300 associate member companies, including manufacturers of raw materials, trade and consumer magazines, and other related industries.

The Soap and Detergent Association is the non-profit trade association representing some 120 North American manufacturers of household, industrial and institutional cleaning products; their ingredients; and finished packaging. SDA members produce more than 90% of the cleaning products marketed in the U.S.

- amend § 333.450(c) to include a modified "Keep out of the reach of children" statement for consumer hand and consumer body product categories i.e. "Keep out of the reach of children except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away."; and
- amend 21 CFR 333 to provide reduced content and format alternatives for small packages of topical antibacterial products in the Monograph.

STATEMENT OF GROUNDS

The following proposal for OTC Monograph labeling of topical antibacterial products is submitted to the Agency by The Soap and Detergent Association (SDA) and The Cosmetic, Toiletry, and Fragrance Association (CTFA) Industry Coalition. The SDA/CTFA Industry Coalition was established in 1994 to respond to the June 17, 1994 Tentative Final Monograph (TFM) for Health-Care Antiseptic Drug Products [59 FR 31401], and since that time has worked with the Agency to progress the final rule-making for the regulation of topical antimicrobial products.

Proposed OTC labeling for topical antibacterial products in the Health-Care Continuum Model

On June 13, 1995 the Industry Coalition submitted detailed comments on the TFM, including an OTC labeling proposal for the product categories in the Health-Care Continuum Model. Recently, the Industry Coalition has re-evaluated and simplified its earlier labeling proposal. The most recent OTC Monograph labeling proposal is provided in Attachment 1 to this Citizen Petition. We respectfully request FDA to disregard the OTC Monograph labeling recommendation outlined in the June 13, 1995 document, replacing it with the attached Health-Care Continuum Model labeling proposal.

Issues associated with the final regulation on standardized content and format requirements (Federal Register March 17, 1999 [64 FR 13253])

Since the TFM was issued in 1994, a Federal Register notice on standardized content and format requirements has been issued. There are two labeling issues associated with implementation of the regulation which need to be considered as part of the rule-making for topical antibacterial products.

- Topical antibacterial products are used by the entire population as part of practicing good hygiene. This includes children who are encouraged to develop the habit of frequent washing early in life. As required by 64 FR 13253, and incorporated into 21 CFR 330.1(g), all OTC drugs must include the general warning "Keep out of the reach of children", followed by the statement "If swallowed, get medical help or contact a Poison Control Center right away" for topical products. For certain product categories in the Health-Care Continuum Model the "Keep out of reach of children" statement is confusing, given that an intended use of safe and effective topical antibacterial consumer and body products is personal hygiene for children.

Following the precedent established by the final Monograph for Anticaries Drug Products, 21 CFR 355.50(c)(1), which allows for the modified warning statement "Keep out of the reach of children under 6 years of age", we request that FDA make provision in the final Monograph for a qualified warning statement for topical antibacterial consumer and body products. FDA recognizes the need for a modified warning statement for dentifrices, and given that toothpastes and topical antibacterial consumer and body products all are intended for promoting good hygiene and will be used by children routinely, we believe that it is logical to allow for a modified warning statement for antibacterials.

For consumer hand and consumer body products the Industry Coalition recommends that the following statement: "Keep out of the reach of children except under adult supervision", followed by the statement: "If swallowed, get medical help or contact a Poison Control Center right away" be incorporated.

- As stated in the Final Rule (64 FR 13253, Section E, comment 35), minimal information is sometimes needed for the safe and effective use of OTC products, and relief from the content and format requirements of 21 CFR 201.66 may be warranted. Compliance with all requirements of 21 CFR 201.66 is often impossible for smaller packages that are commonly used for topical antimicrobials – yet these packages provide consumers with product benefits as a convenient easy-to-use form. The Industry Coalition encourages FDA to provide reduced content and format alternatives for small packages of topical antibacterials in the final rule-making for 21 CFR 333.

ENVIRONMENTAL IMPACT

According to 21 CFR 25.31(c), this petition qualifies for a categorical exclusion from the requirement for submission of an environmental assessment.

ECONOMIC IMPACT


According to 21 CFR 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of the petition.

CERTIFICATION

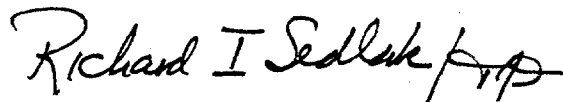
The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data known to the petitioner which are unfavorable to the petition.

Thank you for your consideration of this petition.

Sincerely,



Thomas J. Donegan, Jr.
Vice President – Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association



Richard I. Sedlak
Vice President of Technical & International Affairs
The Soap and Detergent Association

ATTACHMENT 1

PROPOSED OTC LABELING FOR TOPICAL ANTIBACTERIAL PRODUCTS

BACKGROUND

On June 13, 1995 the SDA/CTFA Industry Coalition submitted detailed comments in response to the June 17, 1994 Tentative Final Monograph (TFM) for Health-Care Antiseptic Drug Products [59 FR 31401]. The comments included an OTC labeling proposal for all product categories in the Health-Care Continuum Model. Recently, the Industry Coalition has re-evaluated and simplified its earlier labeling proposal, and requests that FDA consider the OTC Monograph labeling recommendation outlined in this document as part of the final rule-making for OTC topical antibacterial products.

The OTC Monograph labeling recommendation provided below supersedes the labeling scheme described in the June 13, 1995 SDA/CTFA submission. We request that 21 CFR 333 be amended to reflect the proposed labeling described in Tables 1-6 for product categories in the Health-Care Continuum Model.

GENERAL LABELING APPROACH

Products falling within the categories of the Health-Care Continuum Model must be labeled in compliance with all appropriate sections of 21 CFR 201 and 21 CFR 330, as well as the final Monograph.

1. Multiple use products: product categories in the Health-Care Continuum Model can be combined (e.g. topical hand product intended for use by healthcare personnel and consumers, or by food-handlers and consumers) provided the products meet the testing and performance criteria relevant to the indications selected for each product category.
2. Multiple use products should include the statement of identity, indications, warnings and directions for use for each product category in one drug facts box or similar enclosure. For multiple use products, a statement of the intended use should precede the specific directions for each use.
3. Statements of identity, indications, warnings and directions for use applicable to each intended use of the product may be combined to eliminate duplicate words or phrases so that instructions to the product user are clear and understandable.

Table 1

Proposed antibacterial labeling for PRE-OPERATIVE SKIN PREPARATION

PRE-OPERATIVE SKIN PREPARATION	
<u>Statement of identity:</u>	<p>'Antibacterial' or 'antiseptic' followed by statement of classification of product form e.g. 'bar', 'gel', 'liquid' etc. and/or product type e.g. 'wash', 'sanitizer', 'rinse' etc., or other appropriate topical product forms or types.</p> <p>Other truthful and non-misleading statements describing the product category should be optional e.g. 'patient skin wash', 'pre-operative sanitizer', 'pre-operative scrub' etc.</p>
<u>Indications:</u>	<p>'For the preparation of skin prior to' (followed by) 'surgery' / 'injections' / 'aspirations' / 'central line insertion' or 'invasive procedures such as intravenous catheters or chest tubes' &/or 'topical application on preoperative sites'.</p> <p>'Decreases' / 'kills' / 'reduces' / 'eliminates' (followed by) 'bacteria that potentially can cause' (followed by) 'disease' / 'infection' / 'nosocomial infection'.</p> <p>'Helps prevent' or 'inhibits' (followed by) 'the growth of' or 'the regrowth of' (followed by) 'bacteria on the skin'.</p>
<u>Directions for use:</u>	<p>The directions described below are illustrative for products that are intended to remain on the skin, or be removed from the skin after application. These directions should be amended appropriately to describe the specific topical product dosage form &/or product type being used.</p> <p><u>Actives intended to remain on skin</u> - 'Cleanse the area & dry thoroughly. Apply product to the operative site prior to surgery' (insert application method/device). Insert other applicable directions, as needed.</p> <p><u>Actives intended to be removed from skin after application</u> - 'Apply product to the operative site prior to surgery' (insert application method/device). 'When product dries, remove immediately with 70% alcohol, or use as directed by a physician'.</p>
<u>Warnings:</u>	<ul style="list-style-type: none"> • Products must comply with the appropriate sections of 21 CFR 201 and 21 CFR 330. • 'Discontinue use if irritation and redness develop. If condition persists for more than 72 hours, consult a doctor'. • For iodine containing products (§ 333.412(e)): 'Avoid pooling beneath the patient'.

Table 2

Proposed antibacterial labeling for SURGICAL SCRUBS

SURGICAL SCRUBS
<p><u>Statement of identity:</u> 'Antibacterial' or 'antiseptic' followed by statement of classification of product form e.g. 'foam', 'gel', 'liquid' etc. and/or product type e.g. 'wash', 'sanitizer', 'rinse', 'scrub' etc., or other appropriate topical product forms or types. Other truthful and non-misleading statements describing the product category should be optional e.g. 'surgical scrub', 'surgical hand scrub', 'skin cleanser' etc.</p>
<p><u>Indications:</u> 'Significantly reduces the number of bacteria on hands and/or forearms prior to surgery and/or patient care'. 'Decreases' / 'kills' / 'reduces' / 'eliminates' (followed by) 'bacteria that potentially can cause' (followed by) 'disease' / 'infection'.</p>
<p><u>Directions for use:</u> The directions described below are illustrative for products that are intended to remain on the skin, or be removed from the skin after application. These directions should be amended appropriately to describe the specific topical product dosage form &/or product type being used.</p> <p><u>With water</u> - 'Remove jewelry. Wet arms & forearms. Apply' (quantity of product) 'to hands & forearms. Scrub thoroughly for' (insert duration). 'Rinse thoroughly'. (Insert applicable directions for repeat washing).</p> <p><u>Without water</u> - 'Remove jewelry. Apply' (quantity of product) 'to hands & forearms. Spread on both hands. Rub thoroughly for' (insert duration) or 'until dry'. (Insert other directions as needed.)</p>
<p><u>Warnings:</u></p> <ul style="list-style-type: none">• Products must comply with the appropriate sections of 21 CFR 201 and 21 CFR 330.• 'Discontinue use if irritation and redness develop. If condition persists for more than 72 hours, consult a doctor'.

Table 3

Proposed antibacterial labeling for HEALTHCARE PERSONNEL HAND PRODUCT

HEALTHCARE PERSONNEL HAND PRODUCT
<p>Statement of identity: 'Antibacterial' or 'antiseptic' followed by statement of classification of product form e.g. 'foam', 'gel', 'liquid' etc. and/or product type e.g. 'wash', 'sanitizer', 'rinse', 'scrub' etc., or other appropriate topical product forms or types. Other truthful and non-misleading statements describing the product category should be optional e.g. 'healthcare personnel hand sanitizer', 'healthcare professional hand wash', 'healthcare personnel hand rinse' etc.</p>
<p>Indications: 'Decreases' / 'kills' / 'reduces' / 'eliminates' (followed by) 'bacteria' (followed by) 'on the hands'. 'Decreases' / 'kills' / 'reduces' / 'eliminates' (followed by) 'bacteria that potentially can cause' (followed by) 'disease' or 'infection'. 'Helps prevent' or 'inhibits' (followed by) 'the growth of' or 'the regrowth of' (followed by) 'bacteria' (followed by) 'on the hands'. 'Helps' (followed by) 'prevent' or 'reduce' (followed by) 'the transfer' or 'the transmission' or 'the spread' or 'the cross-contamination' (followed by) 'of bacteria'.</p>
<p>Directions for use: The directions described below are illustrative for products that are intended to remain on the skin, or be removed from the skin after application. These directions should be amended appropriately to describe the specific topical product dosage form &/or product type being used.</p> <p>Water Use (before applying product and rinsing): 'Wet arms, (optionally) forearms or other body sites. Apply' (quantity of product) 'to hands, (optionally) forearms or other body sites'. (Select) 'Wash or scrub thoroughly for' (insert duration). 'Rinse thoroughly'. (Insert applicable directions for repeat washing).</p> <p>Water Use (rinse only after using product): 'Apply' (quantity of product) 'to hands, (optionally) forearms or other body sites'. Select 'Wash or scrub thoroughly for' (insert duration). 'Rinse thoroughly'. (Insert applicable directions for repeat washing).</p> <p>No Water Necessary: 'Apply' (quantity of product) 'to hands, (optionally) forearms or other body sites. Spread on both hands, (optionally) forearms or other body sites. Rub thoroughly for' (insert duration) or 'until dry'. (Insert other directions as needed.)</p>
<p>Warnings:</p> <ul style="list-style-type: none"> • Products must comply with the appropriate sections of 21 CFR 201 and 21 CFR 330. • 'Discontinue use if irritation or redness develop. If condition persists, consult a doctor'.

Table 4

Proposed antibacterial labeling for FOOD HANDLER PRODUCT

FOOD HANDLER PRODUCT
<p><u>Statement of identity:</u> 'Antibacterial' or 'antiseptic' followed by statement of classification of product form e.g. 'foam', 'gel', 'liquid' etc. and/or product type e.g. 'wash', 'sanitizer', 'rinse', 'dip' etc., or other appropriate topical product forms or types. Other truthful and non-misleading statements describing the product category should be optional e.g. 'food handler hand sanitizer', 'food handler hand dip', 'food handler wash' etc.</p>
<p><u>Indications:</u> 'Decreases' / 'kills' / 'reduces' / 'eliminates' (followed by) 'bacteria' (followed by) 'on the hands' (followed by, if desired) 'before and after handling food'. 'Decreases' / 'kills' / 'reduces' / 'eliminates' (followed by) 'bacteria on the hands that potentially can cause' (followed by) 'disease' or 'foodborne disease' or 'foodborne illness'. 'Helps' (followed by) 'prevent' or 'reduce' (followed by) 'the transfer' or 'the transmission' or 'the spread' or 'the cross-contamination' (followed by) 'of bacteria'.</p>
<p><u>Directions for use:</u> Provide usage directions consistent with the product form.</p>
<p><u>Warnings:</u></p> <ul style="list-style-type: none">• Products must comply with the appropriate sections of 21 CFR 201 and 21 CFR 330.• 'Discontinue use if irritation or redness develop. If condition persists, consult a doctor'.

Table 5

Proposed antibacterial labeling for CONSUMER HAND PRODUCT

CONSUMER HAND PRODUCT	
<u>Statement of identity:</u>	<p>'Antibacterial' followed by statement of classification of product form e.g. 'foam', 'bar', 'gel', 'liquid' etc. and/or product type e.g. 'wash', 'sanitizer', 'rinse', 'soap' etc., or other appropriate topical product forms or types.</p> <p>Other truthful and non-misleading statements describing the product category should be optional e.g. 'antibacterial hand soap', 'antibacterial hand gel', 'antibacterial hand towelette' etc.</p>
<u>Indications:</u>	<p>'Decreases' / 'kills' / 'reduces' / 'eliminates' (followed by) 'bacteria' (followed by) 'on the hands' (followed by, if desired) 'after changing diapers / attending day care / caring for (sick or elderly or invalid) family members, individuals or people'.</p> <p>'Helps prevent' or 'inhibits' (followed by) 'the growth of' or 'the regrowth of' (followed by) 'bacteria' (followed by) 'on the hands'.</p> <p>'Helps' (followed by) 'prevent' or 'reduce' (followed by) 'the transfer' or 'the transmission' or 'the spread' (followed by) 'of bacteria on the hands'.</p>
<u>Directions for use:</u>	<p>Due to customary conditions of use, directions for use may not be required. Non-customary topical dosage forms or delivery systems should include directions which reflect the conditions used when the product was tested.</p>
<u>Warnings:</u>	<ul style="list-style-type: none"> • Products must comply with the appropriate sections of 21 CFR 201 and 21 CFR 330. • 'Keep out of the reach of children except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away'. • No category warnings are required. Individual warning statements may be required for specific ingredients.

Table 6

Proposed antibacterial labeling for CONSUMER BODY PRODUCT

CONSUMER BODY PRODUCT
<p><u>Statement of identity:</u> 'Antibacterial' followed by statement of classification of product form e.g. 'foam', 'liquid', 'bar', 'gel' etc. and/or product type e.g. 'wash', 'soap', 'rinse' etc., or other appropriate topical product forms or types. Other truthful and non-misleading statements describing the product category should be optional e.g. 'antibacterial body gel', 'antibacterial foam wash' etc.</p>
<p><u>Indications:</u> 'Decreases' / 'kills' / 'reduces' / 'eliminates' (followed by) 'bacteria' (followed by) 'on the skin'. 'Helps prevent' or 'inhibits' (followed by) 'the growth of' or 'the regrowth of' (followed by) 'bacteria' (followed by) 'on the skin'.</p>
<p><u>Directions for use:</u> Due to customary conditions of use, directions for use may not be required. Non-customary topical dosage forms or delivery systems should include directions which reflect the conditions used when the product was tested.</p>
<p><u>Warnings:</u></p> <ul style="list-style-type: none">• Products must comply with the appropriate sections of 21 CFR 201 and 21 CFR 330.• 'Keep out of the reach of children except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away'.• No category warnings are required. Individual warning statements may be required for specific ingredients.