inda Association of the
Nonwoven Fabrics Industry

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

RE: Docket Number 00N-1520, "Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency, Change from 'Junior' to 'Light'" (65 Federal Register 202, pp. 62317-62319)

Dear Dockets Management Branch Officer:

I am writing on behalf of INDA, Association of the Nonwoven Fabrics Industry, in response to the request for comments published by FDA in the October 18, 2000 edition of the *Federal Register* regarding a proposed change of the current "junior" designation for tampons that absorb 6 grams (g) of fluid, and under, to a designation of "light." While INDA supports this proposed change, we have two major concerns which we feel should be addressed prior to changing the current designation.

Basis of Comment

INDA is the internationally-recognized trade association of the nonwoven fabrics industry. Nonwovens are a multi-billion dollar industry in the United States, and are used in scores of durable and short-lived applications. Among other things, for instance, nonwovens are a primary component in tampons and other feminine hygiene products, and INDA has organized a Feminine Hygiene Task Force that includes manufacturers of the vast majority of branded and private-label tampons sold in the United States. Included in this Task Force are companies such as First Quality Enterprises, Kimberly-Clark Corp., the Personal Products Company, Playtex Products, Inc., and Procter & Gamble.

These INDA members have extensive expertise on tampon-related issues, and it is on their behalf that INDA is filing these comments.

INDA's Concerns

INDA stresses that, overall, we believe that FDA's decision to alter the current designation of tampons that absorb 6g or less of fluid from "junior" to "light" is sound, and should be implemented with all due haste so that consumers will know that the designation refers to menstrual flow rather than a consumer's age.

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Effective Date

That said, however, INDA takes issue with FDA's effective date contained in the proposed rule. Simply stated, INDA does not believe that 90 days after publication of the final rule in the *Federal Register* allows sufficient time for manufacturers to alter labeling and artwork on retail packages, as well as deplete their inventories of existing packaging materials.

Instead of a 90-day effective date, therefore, INDA suggests that FDA allow a 24 month period following publication of a final rule in the *Federal Register* during which tampons that absorb 6g or less of fluid could be sold with either a "junior" or a "light" designation. After this 24-month period, INDA recommends that only those tampons which have a valid date code within 24 months of publication of the final rule in the *Federal Register* be allowed to carry the "junior" designation.

Considering that the "junior" designation has been in place for decades — and there is no indication that human health or safety would suffer any increased risk by allowing tampons with this designation to remain on the market during a 24 month transition — INDA contends that manufacturers should be given sufficient time to implement the absorbency designation change on product package labeling. Moreover, it is INDA's understanding that FDA has established a precedent for this type of approach when the Agency implemented metric conversion requirements.

North American Harmonization

In addition to the effective date, INDA is concerned by the fact that — when FDA adopts the proposed designation change — the "junior" designation will continue to be used in Canada, while the "light" designation will be used in the United States. This will require manufacturers who sell to both markets to use different labeling which could result in unnecessary cost increases, continued consumer confusion, and labeling errors.

Because we agree that "light" is the preferred designation, we urge FDA to work with its counterparts in the Canadian Health Protection Branch (HPB) in an effort to harmonize U.S. and Canadian regulations with regard to this designation.

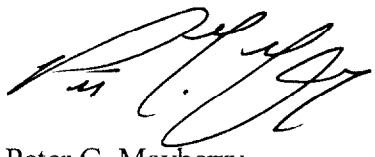
INDA also points out that this dichotomy between U.S. and Canadian absorbency designations applies to tampons that absorb 15-18g of fluid as well. While the U.S. designation for tampons with this absorbency range is "ultra," those tampons sold in Canada with the exact same absorbency levels must be designated "ultra plus." Again, this is an area where INDA is concerned that different labeling requirements for products with the same absorbency ranges sold in both the U.S. and Canada will lead to consumer confusion, increased prices, and potential errors. We urge FDA, therefore, to work with the Canadian HPB on this important issue as well.

Conclusions

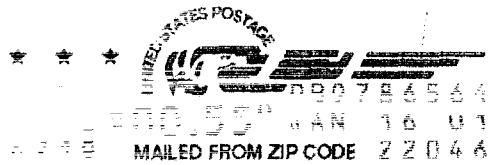
INDA thanks FDA for the opportunity to file comments on this important issue. As we noted in our comments to the Agency's "ultra" designation proposal, INDA members view the issue of "light" versus "junior" as an important matter that should be addressed with all due speed. But we strongly urge FDA to grant tampon manufacturers sufficient time to implement the change, and to work with Canadian officials in an effort to harmonize each of the tampon absorbency designations so that costs, potential confusion, and the potential for labeling errors are minimized.

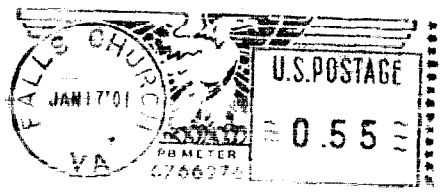
Please feel free to contact me should you have any questions or need additional information regarding any portion of these comments.

Sincerely,



Peter G. Mayberry
Director of Government Affairs





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