# Procter&Gamble

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January 15, 2001



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re.: Docket No. 00N-1520 – "Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency, Change From "Junior" to "Light"

Dear Sir or Madam:

This provides 2 copies of comments from The Procter & Gamble Company (P&G) on the above-cited proposed rule, as requested by the *Federal Register* notice of October 18, 2000 (65 FR 62317). P&G appreciates the opportunity to provide our perspective on this proposed rule.

P&G currently markets TAMPAX® unscented menstrual tampons and Always® unscented menstrual pads and pantiliners within the United States. Based on our experience in the feminine hygiene business, we feel it is important that the product label provide women with accurate, unambiguous information to help them choose the most appropriate products to meet their individual feminine hygiene needs.

P&G supports FDA's proposal to change the absorbency term for tampons that absorb 0-6 grams of fluid from "Junior" to "Light" in the current tampon labeling regulation [21 CFR 801.430(e)(1)]. We agree with FDA's position that this change will reduce the mistaken impression held by many women that Junior absorbency tampons are intended only for younger, teenage women. This nomenclature change will encourage women to use the lowest absorbency tampon appropriate for their menstrual flow.

While we agree with the change in the absorbency term from the "Junior" to "Light" in the proposed rule, we have two concerns with how this change will be implemented following eventual publication of the final rule:

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**1. The effective date in the proposed rule does not allow sufficient time for tampon manufacturers to use up stocks of existing packaging materials, nor to revise the labeling for new packaging materials.**

Section II ("Effective Date") of the proposed rule states that the revised regulation will become effective 90 days after publication of the final rule in the *Federal Register*. This 90-day interval between publication of the final rule and full compliance with its requirements does not allow sufficient time for tampon manufacturers to use up existing stocks of "old" tampon packaging materials (retail packages and insert leaflets) labeled with the "Junior" absorbency term. Since manufacturers will have no way of knowing when the final rule will be published, they will not know when to start reducing their inventories of the "old" packaging materials without endangering their ability to meet market demands for tampons. Normal inventories of packaging materials, in many cases, exceed a 90-day supply. Compliance within 90 days would impose an unjustified economic burden on tampon manufacturers if they are forced to discard any unused "old" packaging materials. Disposal of unused "old" packaging materials could also result in an unnecessary environmental burden and a waste of resources.

This 90-day interval is also insufficient to permit tampon manufacturers to obtain revised packaging materials labeled with the "Light" absorbency term for their full line of tampon retail packages. For example, P&G currently markets more than 30 different TAMPAX tampon retail packages in the U.S. Since each of our retail packages includes discussion of the current Junior absorbency category, labeling for all our retail packages will have to be changed by the compliance date of the final rule. The package design studios and packaging material suppliers we use are simply not capable of making this number of labeling changes within 90 days.

Recommendation:

P&G proposes that the effective date of this regulation be established as **24 months** after publication of the final rule in the *Federal Register*. This would allow each tampon manufacturer to make an orderly and economical transition from "old" to "new" packaging materials. Existing stocks of retail packages and insert leaflets labeled with the "Junior" term could be run out and replaced with new packages and leaflets labeled with the "Light" term as they become available. During the 24-month compliance window, either "Junior" or "Light" would be acceptable terms for describing tampons that absorb 0-6 grams of fluid. Only tampons manufactured and packaged prior to the compliance date could be legally marketed with "junior " labeling after the compliance date. All tampons manufactured and packed on or after the compliance date would have to use the term "Light" in labeling.

**2. Substituting "Light absorbency" for "Junior absorbency" in the U.S. tampon labeling regulation will result in a discontinuity with current Canadian tampon labeling requirements.**

Currently, Canadian labeling requirements allow only the term "Junior" to describe tampons which absorb 0-6 grams of fluid. When this proposed rule becomes effective, such tampons marketed in the U.S. will have to be labeled "Light", while the same tampons marketed in Canada will have to be labeled "Junior". Manufacturers who market tampons in North American packaging that meets current labeling requirements in both the U.S. and Canada will be forced to develop separate packaging for the U.S. and Canada, resulting in unnecessary production costs and logistical costs to manage product segregation and shipment to either the U.S. or Canada. This may also lead to confusion among consumers who have access to both U.S. and Canadian tampon packages.

Recommendation:

P&G strongly urges FDA to initiate harmonization discussions with the Canadian HPB to ensure that the same tampon absorbency terms are acceptable in both the U.S. and Canada. These discussions should begin at the earliest possible opportunity to ensure full North American harmonization by the compliance date of the eventual final rule. The 24-month compliance interval recommended in item 1 of these comments will provide additional time to achieve this harmonization.

As a member of INDA, the Association of Nonwoven Fabrics Industry, P&G has participated in the preparation of comments from INDA on this proposed rule through its Feminine Hygiene Task Force. P&G fully supports and endorses these INDA comments.

Thank you for the opportunity to comment on this proposed rule. We hope these recommendations will help FDA develop tampon labeling that is more informative for consumers and that meets the Agency's needs, but that does not impose undue burdens or unrealistic deadlines on tampon manufacturers.

Please contact me at (513) 634-5196 if you have any questions about these comments.

Very truly yours,

THE PROCTER & GAMBLE COMPANY

Mark M. Anderson, Ph.D.
Regulatory Affairs Manager
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