

# Playtex

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Md. 20857

Dear Sir/Madam:

In response to FDAs reopening of the administrative record and request for comments on the Final Sunscreen Monograph published in the Federal Register of June 8, 2000 (65 FR 36319-36324), Playtex Products Inc., as a final formulator of sunscreen products, offers the following:

- (1) We believe, and will demonstrate, that there is a continued consumer need for labeling SPF's above 30 with the specific SPF number.**
- (2) The test method and criteria for claiming UVA protection should encourage manufacturers to provide such products and the labeling should be simple and clear so as to not to become confused with the SPF designation.**
- (3) The Effective Date of the Monograph must be extended to avoid significant economic burdens from being placed on the industry and passed on to the consumer as a result of having to prematurely destroy good product. It will also allow adequate time to re-label and re-formulate products to meet the requirements of the Final Monograph.**

#### UVB Testing and Labeling

Playtex very strongly believes that there continues to be a need for labeling products above SPF 30 with the product's specific SPF number, particularly for consumers with sensitive skin, those who work outdoors and those with a high risk for skin cancer. Only in this way can they make informed choices at the point of sale about the level of protection they are purchasing. A presentation on "High SPF Sunscreens: A Dermatologist's Viewpoint" was made to FDA in July 1999 by Mark Naylor, M.D. from the Department of Dermatology, University of Oklahoma Health Sciences Center. In his presentation, Dr. Naylor identified the high-risk individuals in the population,

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emphasized the wide range of MEDs existing in different U.S. cities and calculated the theoretical lifetime MED reduction as a function of SPF. Using Ft. Worth, Texas as an example, he demonstrated a 40% reduction in cumulative MEDs reaching the skin over a two-year period when SPF 50 was used vs. SPF 30. All of Dr. Naylor's data pointed to the need for high SPF products, including SPFs above 30 (see Attachment 1.)

Playtex has participated in the drafting of, and fully endorses the position of, the Cosmetic Toiletry and Fragrance association on SPF-related issues, including the language informing consumers that high SPF products are not intended to be used for extending the time spent in the sun and that use, and frequent re-application of, sunscreens are just one factor in a comprehensive sun protection program.

## UVA

After reviewing the pros and cons of the various in vitro and in vivo tests, interpretations of their results and positions taken by L'Oreal (March 3, 2000 submission to Docket No. 78N-0038), Procter and Gamble (May 2, 2000 submission to Docket No. 78N-0038) Dr. Brian L. Diffey, PhD, DSc, Professor of Medical Physics, Professor of Photobiology (in his letter to FDA dated May 26, 2000 to Docket No. 78N-0038), the American Academy of Dermatology and the scientific literature, Playtex is of the strong belief that clarity and simplicity in both labeling and test method for expressing and measuring UVA protection is needed so as to (1) not interfere or overlap with the measurement of erythema, as measured by SPF, (2) to ensure that consumers are adequately educated about the role of UVA protection in suncare and (3) to ensure that the products perform adequately and deliver the appropriate level of protection. Playtex also believes that the standard for a UVA claim should be set at a level that provides a significant measure of protection against UVA radiation in as wide a selection and number of products as possible.

### UVA Labeling

Playtex strongly believes that a single claim, such as "provides broad spectrum protection against UVB and UVA radiation" is essential in order to maintain simplicity and maximize consumer comprehension. This was most recently demonstrated in the market research presented by Procter and Gamble at the American Association of Dermatologists (AAD) Consensus Conference on UVA Protection of Sunscreens on Feb.4, 2000. In this research, different SPF/UVA labeling formats (including a graphical description of UVA protection) were presented to over 2,000 consumers. The label that simply stated "UVA/UVB Protection" in addition to a prominently displayed SPF number was found to be superior with regard to ease of product selection, selection of the higher level of protection and of SPF as the primary indicator of sunscreen efficacy. This confirmed the results of a previous Schering Plough study among 235 consumers who concluded that a descriptive approach better conveys to consumers the added benefit of UVA protection and did not detract from the SPF.

This research confirms Playtex's belief that a labeling framework containing multiple levels of UVA protection combined with different SPF numbers will cause widespread consumer confusion. For instance, some consumers might use products with "high" UVA protection combined with a low SPF rating thinking they are getting the same or more protection as they would be getting from the use of a high SPF product. This, of course, would be contrary to what FDA, dermatologists and manufacturers are trying to achieve.

### Test Method

Since, unlike UVBs erythemogenic effect, there is no generally accepted, clear in vivo visual or biological end point for UVA exposure, the need for a reliable, scientifically valid in vitro measurement is critical. The simplicity and inherent scientific logic of the critical wavelength method as described by Diffey, which measures the breadth of the UV spectrum absorbed by a given product, meets these requirements.

By definition, it allows for broad-spectrum activity regardless of the SPF so that if a consumer chooses to use a low SPF product they will at least have the option of choosing one that provides a wide breadth of activity. If a product has a high SPF and a broad spectrum claim is to be made, the appropriate amount of UVA absorbing ingredient or ingredients must be added to satisfy the requirements of the critical wavelength chosen. That is, at least 90% of the area under the spectral curve must fall below the critical wavelength.

### Critical Wavelength

In the 1993 Tentative Final Monograph (58FR 28233), FDA cites a NIH consensus development statement on sunlight, UVA radiation and the skin. Specifically, it states that "recent evidence suggests that the longer UVA wavelengths (i.e. UVA I, 340-400nm) are less damaging than shorter UVA wavelengths (i.e., UVA II, 320-340 nm), but further research is needed to confirm the distinction".

FDA goes on to state that in order to "offer significant UVA protection" a "sunscreen ingredient must have an absorption spectrum extending to 360nm or above, in order to display UVA protection claims in its labeling". FDA then lists several Category I sunscreen ingredients that meet this criterion.

Playtex agrees with FDA's assessment that an absorbance threshold of 360nm covers the most critical part of the spectra in terms of biological effects.

The fact is, there are a number of sunscreen products being marketed today with critical wavelengths of 360nm but consumers are not aware of them.

This was confirmed by Diffey's determination of the critical wavelengths of 59 commercial sunscreen products with SPFs between 4 and 45, which he presented at the AAD Consensus Conference referred to above. About 70% of the critical wavelengths were between 340nm and 360nm with only 10% of the products above 370nm (see Attachment 2.)

Thus, by selecting 360nm as the criterion, FDA would make immediately known and available to a majority of consumers, products that provide protection against the more erythemogenic, and potentially more harmful, portion of the UVA spectrum.

If, on the other hand, FDA were to arbitrarily select a higher standard, e.g., 370nm (the incremental clinical benefit of which vs. 360nm has not been demonstrated) it would create several issues. It would result in a major reformulation effort within the industry, higher prices to consumers and delay the introduction into the marketplace of fewer "broad spectrum" products than would otherwise be available if the 360nm critical wavelength were selected.

### **Effective Date of the Monograph**

We presume for this submission that the details of the Final Monograph will be known on December 31, 2001.

If this occurs, in order to be most effective in avoiding a huge economic impact on the suncare industry and consumers, the Effective Date of the Monograph should commence August 1, 2003 for suncare products **manufactured** after that date. FDA's proposed Effective Date of December 31, 2002 for **shipping** would not solve the problem.

The dynamics of the suncare industry are unique in that returns from retailers after the suncare season amounts to 25-30% of annual shipments or upwards of \$200 million for the industry in one season. These returns are resold the next sun season. **Adopting an Effective Date of August 1, 2003 for goods manufactured on or after that date, would ensure that the bulk of product for the 2004 season would be re-formulated and re-labeled in accordance with the Monograph and would provide for the reshipment of returns from the 2003 season.** (The proposed Final Monograph issuance date of December 31, 2001 does not allow enough time to re-formulate and re-test products for manufacture in 2002).

Use of a "manufacturing date" is a method that has been used for dealing with this kind of problem. If instead a "shipping date" is used, the Effective Date would have to be July 1, 2004, **almost a full year later**, in order to avoid the huge economic impact created by the returns situation and to allow adequate time for re-formulating and re-testing the new products.

The reasons for this recommendation are provided in more detail below and a chart showing the relevant dates is attached:

- (1) Although we encourage consumers to use sunscreen products daily, the fact is that a significant part of the business remains largely seasonal: in general, the preponderance of product is shipped by manufacturers to retail during approximately January-June of Year 1; it is sold by retailers to consumers from approximately May-August; retailers ship returns back to manufacturers from

September-February; manufacturers reship them to retailers in January of Year 2 for resale to consumers in May. This shipping process takes 18 months to complete.

- (2) Until the Final Monograph issues, manufacturers will not know what (a) the final labeling requirements are, (b) what possible requirements will be required for SPF testing, (c) what the new UVA test requirements will be and (d) the extent of the re-formulation that will be required to meet new and/or existing label claims.
- (3) The following timetable shows in more detail the reasons for the required extensions in the effective date.

**TIMING REQUIRED TO DEVELOP PRODUCTS THAT MEET THE REQUIREMENTS OF THE FINAL MONOGRAPH AND ALLOW FOR SHIPMENT OF THE PREVIOUS YEAR'S RETURNS.**

**(18 MONTHS – IF BASED ON SHIPMENT DATE)**

**2001**

Jan –June	Ship 2001 Product and 2000 Returns
Sept – Feb	2002 Product +2001 Returns sold in
Dec 31, 2001	Final Monograph – details known

**2002**

Jan –June	Ship 2002(OP) and 2001 (OP>Returns
Jan	Begin New Product Development (which will take 12-15 months)
Sept –Feb	2003 (OP) +2002 Returns sold in

**2003**

Jan – June	Ship 2003 (OP) and 2002 Returns
April	New Product Materials ordered
Aug	New Product Produced
Sept – Feb	2004 NP + 2003 Returns (OP) sold in

**2004**

Jan –June	Ship 2004NP and 2003 Returns (OP)
July	EFFECTIVE DATE of Final Monograph Based on shipment date

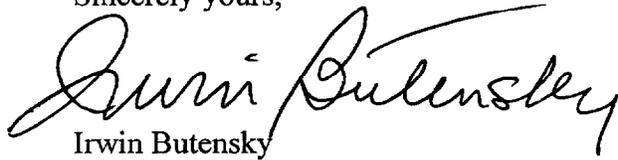
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OP = Product before Final Monograph                      NP = Monograph compliant

In summary, Playtex, as a major manufacturer of sun care products, understands the complexity of the category from both the business and scientific aspects, and has based its comments on this experience.

We appreciate FDA's willingness to work with the industry over the years and believe our comments, if adopted, will help to resolve several of the more important issues to the benefit of all concerned.

Sincerely yours,



Irwin Butensky

Attachments:

- (1) Dr. Naylor's presentation to FDA re high SPFs
- (2) Dr. Diffey's presentation to AAD on Critical Wavelength Method