

Procter & Gamble

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Health Care Research Center
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March 21, 2000

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

Re: FDA Docket No. 96N-0277; 64 Fed. Reg. 71062,
December 20, 1999; Additional Criteria and Procedures for
Classifying Over-the-Counter Drugs as Generally Recognized as
Safe and Effective and Not Misbranded; Proposed 21 CFR
§§ 330.13 (e) and 330.14

Procter & Gamble (P&G) respectfully submits these comments on the proposed regulations published by the Food and Drug Administration (FDA) for "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded."

Background

On October 3, 1996, FDA published an Advance Notice of Proposed Rulemaking (ANPR) on this subject (61 Fed. Reg. 51625). P&G filed comments with FDA on January 2, 1997, in which we declared our support for the inclusion of foreign-marketed ingredients and the establishment of comparable standards to those applied to domestic OTC ingredients. We also stated that the consideration of the safety and effectiveness of these ingredients should be based upon the quality of the data, not upon arbitrarily selected material times, material extents or listing of countries. The establishment of very specific requirements for material time, material extent and marketing experience reduces the first consideration of foreign marketing data to an administrative effort and eliminates good judgment from the process.

Data Requirements

P&G maintains that, in the proposed rule, the agency has established even more specific requirements than in the ANPR, which compounds the complexity of establishing material time and material extent for OTC monograph conditions. Overall, the proposed rule has made the process impractical and prohibitive by establishing data requirements that are unrealistic. While the agency maintains the proposed criteria and procedures are intended to be "general in nature", i.e., a "regulatory framework", the requirements are actually very detailed. Also, the proposed rule states "the agency intends to apply the criteria and use its judgment in specific situations." We reiterate our position that the agency should simply provide guidance/points to consider for material time, material extent and marketing experience, rather than specifying extensive data requirements which are unrealistic in scope, and impossible to meet. The main considerations for inclusion of a foreign-marketed ingredient into the monograph should be the same today as when the monograph system was established, i.e., the judgment of the safety and effectiveness of the ingredient based on the best data available.

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The scope of the proposed ruling is quite narrow and restrictive. For example:

1) Indication wording may differ in countries outside the United States. Data from the exact condition should not have to be demonstrated; a similar condition should be considered, i.e., the actual use, not just that defined by the regulatory wording; 2) A drug that is sold OTC in one or more countries will be disqualified from the monographs because it is marketed by prescription in the US. Also, if a product is sold Rx or in a pharmacy only in other countries, it must be demonstrated that this marketing restriction does not indicate safety concerns; and 3) The definition of "condition" includes "dosage form", yet most OTC drug monographs do not limit dosage forms. There may be situations where it is necessary to require the marketing experience for a novel or special dosage form, but this should apply only to those monographs where dosage forms are specified and not to monographs where there are currently no dosage form restrictions.

Time and Extent Applications and Interim Marketing

If an ingredient has been sold in the US for a material time and extent for a similar indication, it should not be necessary to submit a "time and extent application" (TEA), for example, inclusion of ibuprofen into the analgesic monograph. The proposal offers only an exemption for providing labeling. Based on the requirements, it could take a long time for the sponsor to gather the information for a TEA, and no time frame is provided for reviewing TEAs in the proposed rule. Thus, if a product is determined to be acceptable in an OTC monograph, P&G believes marketing should be allowed before the monograph is finalized, given the length of time it has taken to finalize many of the OTC monographs. Examples of where interim marketing in the OTC Review have been accepted prior to monograph finalization are sensitive teeth dentifrices and sunscreens.

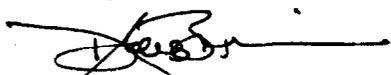
Summary

Procter & Gamble agrees that if "conditions" not previously marketed in the US were to obtain OTC drug monograph status and a greater selection of OTC drug products became available, this would benefit consumers. We support the development of appropriate criteria for the inclusion of foreign-marketed ingredients into the US Over-the-Counter (OTC) monograph system, but suggest the FDA criteria in the proposed rule are too specific and therefore limiting. P&G believes the ingredients should be evaluated for their safety and effectiveness on the same scientific criteria used to include other ingredients in the US monographs.

In addition, P&G supports the position of the Consumer Healthcare Products Association as submitted to this docket.

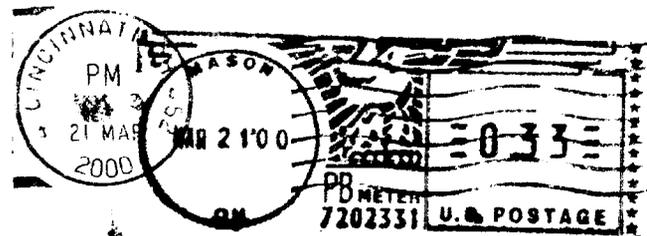
We thank the agency for its consideration of these comments.

Sincerely,



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