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February 20, 2001

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

Re: Docket no. 00D-1584
Guidance for Industry:
Labeling OTC Human Drug Products -
Submitting Requests for Exemptions
and Deferrals. Availability published in
Federal Register December 19, 2000
[65 FR 79371]

On December 19, 2000 the Food and Drug Administration published the availability of a draft guidance on the Labeling OTC Human Drug Products - Submitting Requests for Exemptions and Deferrals [Docket No. 00D-1584]. The agency requested comments on the draft by February 19, 2001.

These comments are submitted on behalf of the Consumer Healthcare Products Association (CHPA), the 120-year-old national trade association representing manufacturers and distributors of nonprescription or over-the-counter (OTC) drug products and dietary supplements. CHPA members account for 90-95% of the volume of OTC drug products sold in the United States. CHPA is thus vitally interested in the draft guidance and its effect on the OTC industry.

General

CHPA believes the draft guidance goes beyond the submission process for petitions for exemption. It implies that no exemptions will be granted based on insufficient labeling space, even though this is the primary reason a company will need an exemption for a given package. It also discourages companies from petitioning for exemption from the minimum type size requirements. As written, the draft guidance is for submitting requests for deferrals, not a guidance for submitting requests for exemptions and deferrals, as its title would suggest.

The rule [21 CFR 201.66 (e)] states that FDA "may exempt or defer, based on the circumstances presented, one or more specified requirements set forth in this section on the basis that the requirement is inapplicable, *impracticable*, or contrary to public health or safety." (Emphasis added.) The draft guidance virtually eliminates the impracticability consideration, concluding that any package can be redesigned or reengineered so that no exemption from the rule is needed.

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If there is to be a legitimate exemption process, as the rule states, it is improper and contrary to the final rule to arbitrarily bar types of exemptions that are specifically allowed by the rule.

At the end of Section IV, What Should I Include in my Application for Exemption, the draft states, "The Agency expects to respond only to the specific exemptions or deferrals requested." While this seems logical on the surface, the implication is that the Agency does not intend to look at a proposed label for overall readability. In fact, no readability factor taken by itself can determine the readability of a label. The final judgement of readability must be made by the human eye, which can integrate all the factors into overall readability.

CHPA believes that the agency should allow for overall readability in its evaluation of applications for exemption. This evaluation should not preclude consideration of any individual readability factors *a priori*, but allow the overall presentation of the label to determine its adequacy. Indeed, the support for 6 point type size as the arbitrary cut point for readability is limited at best. Allowing for data to drive a decision about readability in the exemption process would more properly define evidence-based decision-making, even if in the process the agency were to find that a type size of less than 6 points incorporated into special formatting is as readable as 6 point type in a similar format. Without the adoption of an evidence-based approach to the exemption process, there is little need for a guidance, and less need for the pretense of a guidance.

A. Applications Based on Insufficient Labeling Space

The agency has said that it will not routinely grant an exemption for products that are too small to meet the requirements of the regulation. It implies that packages can be modified to accommodate the rule as written, and the Agency expects manufacturers to use alternative design techniques to increase available labeling space to be able to comply with the rule.

Inadequate space is precisely the reason that most exemptions will be needed. This is where the practicability consideration of the rule should apply. If it were possible or practicable to reconfigure or re-engineer the packaging to meet the final regulation, no exemption would be necessary. Therefore, this section of the guidance is meaningless in a practical sense. In the OTC market, practicability relates not only to changing a package, but to the acceptability of that package by the retail trade. If a package can be physically increased in size, but then will not be accepted by the retail trade, it is impracticable because it cannot be sold.

If the agency accepts applications for exemption, as the rule specifies, and not just applications for deferral, it must seriously consider those as applications for exemption, without prejudging them. An exemption should mean that the rule, or parts of the rule, will not apply to the package for which the exemption is requested. It should not mean that compliance will always be required, but may be deferred.

In view of this, the section on Applications Based on Insufficient Labeling Space should be rewritten to give industry realistically practical guidance on submitting applications for exemptions that will be reasonably and carefully considered by the OTC Division.

B. Applications Requesting the Use of a Reduced Type Size

The draft states that "type size exemptions generally will not be granted. We emphasize that by issuing a blanket veto of certain types of exemptions to the rule, FDA is prejudging the issue, and fails to adhere to the exemption provisions of its own rule. CHPA has shown the agency on more than one occasion that type size is but one factor of many that determine readability. There are cases where certain combinations of readability factors may be used to result in greater readability for smaller type sizes than for larger ones. Our conclusions are based on a thorough study of the world literature on readability, and demonstrations of these readability principles. On the other hand, the agency's determination that 6-point type should be an absolute minimum is based on a misinterpretation of a single study, which actually showed the opposite of FDA's conclusion.

If the exemption process is to be honest and meaningful, type size must be included in the parts of the rule subject to the exemption process. As stated above, the human eye should judge readability, and the acceptability of a proposed departure from the requirements of the rule, based on the totality of the label. Without the incorporation of an evidence-based approach to readability in the exemption process, there is little need for a guidance. One can only speculate that, if FDA continues to steadfastly refuse to consider a data-driven approach to defining readability (including type size) in the exemption process, then the agency is only arbitrarily protecting its previous decision in the final rule to establish 6 point type as the *a priori* minimum size – a minimum type size that, as stated, had very limited support.

C. Applications Relating to the Listing of Inactive Ingredients

We compliment the agency for approving one application relating to the composition of the list of inactive ingredients. Where different suppliers are used, and the exact composition of inactive ingredients may differ from batch to batch, FDA allowed the petitioner to use the words *may contain* followed by a listing of those ingredients that may or may not be contained in the particular batch of product. This ruling assures the consumer will have complete information related to ingredients to which the consumer might be allergic or sensitive, while allowing the manufacturer needed purchasing flexibility.

In referring to this approval, the draft guidance suggests that further approvals of a similar nature would be favorably considered. It is inconclusive, however, and would still require individual applications for other products and packages. If this type of inactive ingredient labeling is acceptable, and we agree that it is, the agency should issue a blanket exemption to cover it. It is inefficient for both the industry and the agency to handle this type of issue on an individual basis. This could be included in the guidance, or issued as a technical amendment to the rule.

Summary

The Consumer Healthcare Products Association believes that the draft guidance needs considerable revision in order to be useful to the OTC industry. In particular:

1. Individual reasons for exemption, such as inadequate space for labeling, should not be prejudged as insufficient reason for exemptions.

2. Impracticability should be reinstated as a reason for exemption, as provided for in the rule.

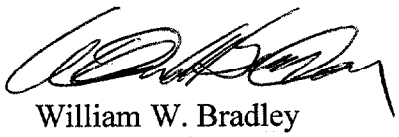
3. No one readability factor, such as type size, should be excluded from consideration in the exemption process.

4. Readability of the label should be considered in its totality, judged by the human eye, and where necessary support by evidence in the form of readability studies.

5. A blanket exemption should be issued covering inactive ingredient labeling, which allows the phrase *may also contain*, or similar wording, to indicate ingredients that may be in some batches of the product, but not all.

These comments are submitted in a spirit of cooperation, and CHPA hopes they are helpful to the agency as it considers the draft guidance.

Sincerely,



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