founded 1881

May 7, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 1998 N-0337C; RIN No. 0910-AD47: Proposed Rule on Labeling Requirements for Over-the-Counter Human Drugs; 71 *Fed. Reg*. 74474 (December 12, 2006)

Dear Sir or Madam:

On December 12, 2006, the Food and Drug Administration (FDA) issued a proposed rule on labeling requirements for over-the-counter (OTC) human drugs (71 *Fed. Reg*. 74474 - 74482). The announcement proposed a definition for "convenience-size" OTC drug packages as well as the option of alternative labeling requirements for these products. The Consumer Healthcare Products Association (CHPA) welcomes the opportunity to comment on the proposed rule changes. Founded in 1881, CHPA is a national trade association representing manufacturers and distributors of OTC products and dietary supplements. Our membership represents approximately 90% of the OTC medicines sold in the United States.

Interested CHPA members agree in principal with most of the points outlined in the proposed rule. However, we do have concerns with certain aspects of the proposed rule which are expressed in this submission. The areas of focus for our comments are related primarily to the labeling and the maximum number of doses allowed for convenience-size OTC products.

Issues Related to Drug Facts Labeling

We support FDA's decision to allow modifications to the Drug Facts (DF) format and wording for convenience-size OTC products. We also agree with the Agency's conclusion that the unique status of these products warrants flexibility in labeling, with a partially truncated label on the outer container. FDA has proposed to allow certain DF information to appear inside the product package. While we support the idea of truncated labels, there may be instances where it is a practical impossibility to include the information inside the package. For instance, pouches that must be torn to access the contents would probably not

Consumer Healthcare Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006
T 202.429.9260 F 202.223.6835
www.chpa-info.org

allow for DF information to be included on the inner package. The concern is that the user may inadvertently destroy the information when opening the package. In addition, incorporation of easy-to-open features intended to preserve label information could defeat both the child-resistant and tamper-evident requirements for certain OTC products. Similarly, a product in liquid or paste form and not sold with an inner and outer package could not pursue this option or include an insert.

As an alternative, CHPA members propose that FDA allow greater flexibility in the formatting permitted for the alternative labeling requirements. Because space is very limited for these convenience products, we recommend that companies be permitted to omit bullets and to use narrative text to provide the required, truncated information. It was noted in the *Fed. Reg.* notice that convenience-size OTC products have a reduced risk associated with their limited contents (71 *Fed. Reg.* 74479).[1] We believe that allowing alternative formatting for labeling would not increase the risk with use of these products.

By their very nature, convenience-size products are designed for immediate or short-term use, so it may reasonable to include some DF labeling information only on the inside packaging or to utilize one of the alternative methods for providing full DF labeling proposed below. Adults purchasing these products are familiar with the appropriate usage of these products as well as applicable warnings. Thereby certain warning statements can be abbreviated. If the required warning statements were consolidated under the "**Ask a doctor before use**" sub-heading, the "**Other information**" section of the DF panel could be eliminated on the outer package, resulting in fewer sub-headings needed and obviating the current need for a fifth label panel. For example, other warnings, such as the alcohol and pregnancy warnings, could be listed in an abbreviated, bullet format under the **"Ask a doctor before use"** section; whereas the cation statement could be provided solely inside the package. In fact, if our recommendations to allow truncated labeling and alternate formatting on the outer package are rejected by the Agency, the labeling changes currently outlined in the *Fed. Reg.* notice, are unlikely to eliminate the need for expanded surface area on convenient-size OTC products. Complete DF labeling could still be provided inside the package or as we propose below.

If the Agency rejects our recommendation to allow narrative text with truncated DF labeling, we propose allowing abbreviated DF labeling on convenience-size products, with full DF information provided in close proximity, as an alternative solution. Possible methods for providing full DF information to consumers prior to purchase include full labeling on the product dispensing box, tear-away sheets similar to those used for cosmetic ingredients, or providing the information as outlined in the Compliance Policy Guide (CPG) for OTC products distributed in vending machines (CPG 7132b.06).[2,3] These alternatives

---

[1] 71 FR 74474 - 74482; Over-the Counter Human Drugs; Labeling Requirements; Proposed Rule. Retrieved April 16, 2007, from: http://www.fda.gov/OHRMS/DOCKETS/98fr/E6-21019.pdf.

[2] 21 CFR 701.3(i) Cosmetic Labeling. Retrieved April 26, 2007, from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=701.3.

[3] Sec. 450.400 Labeling and Distribution of OTC Drugs in Vending Machines (CPG 7132b.06). Retrieved April 5, 2007, from http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg450-400.html.

would allow consumers to make an informed decision prior to purchase but not precipitate the need for alternative packaging. An added advantage of allowing tear-away sheets at the point of purchase is that the sheets could also be used as a handy reference for later use. If an increase in package size is required to accommodate full DF labeling, it may result in products that are no longer "convenience-size" and therefore no longer offered by manufacturers.

Issues Related to Dose

FDA has proposed that for products marketed with directions for both adults and children, dose should be defined as the maximum single serving based on the child's dose and that this proposed definition apply only to packages that contain only one or two dosage units of an OTC drug. While we agree that there should be a limitation to the amount of product contained in a convenience-size OTC medicine, we feel there are certain instances where these conditions may be too restrictive. It is impractical to supply certain products as convenience-size OTC products for adults if they are limited to two children's dosages.

For example, the child's dose for toothpaste is a pea-size amount. If a maximum of two child dosages were provided in the package, it would not be an adequate amount to be meaningful for adults. Although not an all-inclusive list, examples of other product categories where limiting the convenience-size product package to a maximum of two child doses is impractical are for anti-emetic, anti-diarrheal, cough-cold, analgesic, antacid, and ophthalmic products. Products, such as dimenhydrinate (an anti-emetic medicine) and loperamide (an anti-diarrheal medicine) are dosed based on age and/or weight. If the maximum dose for the youngest consumer is used to determine the maximum number of doses in the package, the convenience-size product would contain only one tablet. Packages containing one tablet would provide the minimum adult dose for the dimenhydrinate products and less than the minimum adult dose for loperamide products, and would prohibit repeated dosing in adult consumers.

As an alternative, we propose that for oral products and orally administered topical products (such as toothpastes), dose be defined as a maximum of two adult doses. Because these products are intended for immediate or short-term use, there is limited opportunity for product misuse or for increased risk by allowing two adult doses. Additionally, these products are purchased primarily by adults and many of them are in child-resistant packaging.

In the *Fed. Reg*. notice, the Agency noted that OTC monographs generally give manufacturers the flexibility to market OTC drugs specifically to adults, children, or both.[1] However, creating separate convenience-size packaging for adult and child usage may not overcome the hurdle of impracticality. This may result in fewer convenience-size products available to children in spite of their public health benefit. Even if companies opted to manufacture each convenience-size product in adult only and child only packages, it is likely that the number of convenience-size OTC medicines would be limited due to shelf space considerations.

CHPA members believe it is practical to expand the number of allowed convenience-size doses for certain product categories where there is limited risk due to the short term, non-repetitive use of the convenience product. We suggest that FDA apply the same criteria used to identify active ingredients and dosage forms appropriate for truncated labeling in the Skin Protectant Final Monograph, mainly:

- Packaged in small amounts
- High therapeutic index
- Extremely low risk in actual consumer use situations
- Favorable public health benefit
- Few specific warnings

as the basis to identify convenience-size OTC medicines where an expanded number of convenience-size doses would be appropriate.[4] For example, for antacid products, consumers are permitted to take several tablets per dose per day, in some cases up to fifteen tablets in a 24-hour period.

FDA has specifically requested comment on whether the agency's proposed definition of "dose" is applicable to topical drug products and how it might be possible to include topical drug products within the convenience-size proposed rule.[1] In the Skin Protectant Final Rule, FDA listed eight criteria which the Agency used in its determination that certain skin protectant active ingredients and product dosage forms could be marketed with truncated drug facts content and alternative drug facts format.[4] Those criteria were:

- Packaged in small amounts
- Applied to limited areas
- High therapeutic index
- Extremely low risk in actual consumer use situations
- Favorable public health benefit
- No specified dosage limitation
- Few specific warnings
- No general warnings (*e.g.*, pregnancy, overdose)

Some categories of topically applied OTC drug products that meet these criteria include those marketed under the following OTC drug monographs: acne; antiperspirants (non-aerosol); first aid antibiotics; first aid antiseptics; external analgesics (for rashes, fever blister/cold sore); healthcare antiseptics – consumer antimicrobial hand sanitizers; opthalmics (*e.g.*, demulcents, emollients); seborrheic dermatitis/psoriasis (non-shampoos); skin protectants; and sunscreens. Generally, product offerings in these categories include small package sizes (convenience, travel, and trial sizes) for personal use throughout the day or as needed; are applied to limited areas (*e.g.*, pimples; underarms; small cuts, scrapes or burns; hands; face; or eyes); are "dosed" by the size of the body surface area to be covered rather than by age; have few specific warnings and only one general warning (*i.e.*, "**Keep**

[4] 68 *FR* 33362, 33372. Skin Protectant Drug Products For Over-The-Counter Use. Final Monograph.

out of reach of children."). Products in these categories provide a public health benefit by providing convenient access to products that may help protect, prevent, or relieve commonly experienced conditions that might otherwise remain untreated in the absence of small package sizes that can be carried in a pocket or purse.

In addition to expected variability in the size of the body surface area to be covered, there is variability in the applied amount of topical drug products. One estimate is that the average self-application of a cream is approximately 2.42 $\pm$ 1.63 mg/cm^2 of skin surface.[5] As a result of variability in the size of body surface area to be covered and the amount of product applied, convenience/travel/trial size packages of topically applied products most often contain more than 2 doses or applications per package. For example, alcohol-based hand sanitizers for out-of-home use are provided in packages that contain as little as 0.5 fl oz (15 ml) or 1.0 fl oz (30 ml) and are recommended for repeated use. A typical "dose" for antimicrobial hand cleansing is approximately 0.7-3.0 ml which would result in 5-21 (15 ml size) or 10-42 (30 ml size) "doses", respectively. Similar reasoning and calculations apply to other topical OTC medicines provided, for example, in lotion, gel, cream, or ointment formulations.

Based on the above discussion, we believe that FDA's proposed definition of "dose" is not appropriate for topically applied drug products. However, we do feel it will be possible for FDA to include such products in the final rule on convenience-size labels if the rule utilizes the amount of available label space rather than dose as the criterion for permitting alternative (truncated) drug facts content and drug facts format.

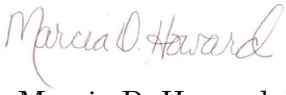
In summary, interested CHPA members generally support the conditions listed in the proposed rule, but hope the Agency will consider the suggestions outlined in this submission. Specifically, we hope FDA will:

1) Allow Drug Facts labeling information to be provided to consumers in narrative format with additional truncation permitted;
2) If truncated Drug Facts labeling in a narrative format is *not* permitted, allow Drug Facts labeling to be provided in a manner other than listing inside the convenience-size OTC product or an insert, such as tear-away sheets;
3) Expand the definition of "dose" to two adult doses for product categories where the potential child-size dose is meaningless for adult use;
4) Expand the number of doses allowed in convenience-size packages beyond two adult doses for certain categories by utilizing the criteria provided in the Skin Protectant Final Monograph[4];
5) Include topically applied OTC drug products in the final rule but utilize amount of available label space rather than "dose" as the criterion for permitting alternative drug facts labeling.

[5] Matveev NV and Maibach HI. 2002. Factors influencing the amount of topical preparations applied. *Exog Dermatol* 1: 64-7 (citing Schalgel CA and Sanborn EC. 1964. The weights of topical preparations required for total and partial body inunction. *J Invest Dermatol* 42: 253-6.)

CHPA members thank the FDA for the opportunity to provide our comments and recommendations on the proposed rule. If there are any questions or if we can be of assistance, please feel free to contact me.

Sincerely,



Marcia D. Howard, Ph.D.
Associate Director, Scientific Affairs

MDH/05-07-07

I:\Committees\SAC\Convenient size OTC Working Group\FDA Submissions\Convenience size FDA submission FINAL ver 9.0 050707.doc