CHPA

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May 25, 2007

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

Re: Docket No. 1977N-0094L, RIN 0901-AF36
Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling, 71 Fed. Reg. 77314-52 (December 26, 2006)

Dear Sir or Madam:

In the December 26, 2006, *Federal Register*, the Food and Drug Administration invited comments on the above-referenced proposed rule, which proposes new warning and other labeling requirements for internal analgesic, antipyretic, and antirheumatic (hereinafter, "internal analgesics") over-the-counter (OTC) drug products.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of OTC medicines and dietary supplements in the United States, including OTC internal analgesics. CHPA members account for over 90 percent of the domestic retail sales of OTC medicines. As such, we have an interest in the subject matter of the proposed rule.

We are committed to communicating important information about the safe use of OTC medicines through labeling, and while a number of CHPA members have already instituted voluntary label changes to communicate the types of information FDA seeks to address in the proposed rule, we seek a number of clarifications or changes in the proposed rule. These revolve around: (1) proposals which impact the principal display panel; (2) highlighting information within the "Drug Facts" label; (3) efficient use of limited label space; and (4) clarifications.

1. Principal display panel proposals.

(a) The proposal to require ingredient names and "(NSAID)" in a type size one-quarter that of the most prominent matter on the principal display panel is unnecessary, not justified, and should be modified. FDA proposes that the active ingredients acetaminophen, aspirin, and nonsteroidal anti-inflammatories (NSAIDs) in addition to

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aspirin be listed on the principal display panel (PDP) in one-quarter size of the most prominent printed matter on the PDP (typically the brand name). FDA similarly proposes to the same treatment for the term "(NSAID)". We do not believe a ratio to the brand name is needed, and FDA presents no data to support an arbitrary one-quarter ratio proposal. The agency could instead require the amended statement of identity to be at least as large as the "Drug Facts" title elsewhere on the outside container. This would assure appropriate prominence of this information, but without crowding the PDP or lessening opportunities for firms to compete through branding.

Even without a one-quarter ingredient-to-brand name ratio, FDA's objective – an objective we agree with – will still be met: Consumers can be assured that each and every internal analgesic product, and including combination products with internal analgesic ingredients, will include active ingredient information on the PDP with appropriate prominence.

The agency's current proposal would crowd the PDP, thus adding a significant burden on a firm's ability to compete in the marketplace. It would lessen the ability of manufacturers to communicate through the core function of their brands. Brands play a key role in assisting consumer purchasing decisions by identifying the source of different products as known and trusted. Brands are the principal repository of good will that enable a company to distinguish its products from those offered by others.

To detract from the ability to clearly brand products imposes a high information costs on consumers, since consumers lose the categorizing assistance of easier, clearer brand communication. For example, when a consumer is in a store aisle looking at potentially hundreds of products, familiarity with known brands acts as a short cut to speed up and narrow the decision-making process. Further, the value and trust consumers place in brands are incentives for firms to drive innovation, which in turn fosters competition in general, brings value to consumers, and helps to keep costs lower for consumers.

Finally, unnecessarily placing prominence on one active ingredient and/or warning may overshadow or otherwise detract from the importance of other active ingredients and/or warnings. In remarks that we recognize do not necessarily represent the opinions of the agency, some FDA officials have noted discomfort in existing labels that highlight or bold selected pieces of information since this could draw the eye to those messages and consequently away from others. Raising the comparative prominence of some information at the expense of other pieces of information also causes companies to undertake legal analyses to assess potential product liability implications of such emphasis.

While CHPA is not suggesting that there be no PDP requirements, we would note that active ingredients (and their purpose) are already the first piece of information in the "Drug Facts" label. All of the information in Drug Facts label is important, not just the active ingredient. Ultimately, it is the Drug Facts label, not the PDP, that should remain the focus in guiding consumer use decisions and actions. As FDA noted in the Drug Facts rule preamble, listing active ingredients first "will enable consumers to quickly and systematically compare ingredients within products for similar uses. In addition, because

the respective purposes will be listed next to each active ingredient, consumers will know why the ingredient is in the product. Regardless of placement on the PDP, such uniform and prominent placement will help to ensure proper product selection, especially for line extensions." 64 Fed. Reg. 13254, 13260 (March 17, 1999). While the PDP is a vital tool in capturing a consumer's attention to trigger an initial, preliminary shopping choice, it is not a substitute for the Drug Facts label, including active ingredients.

The Drug Facts rule preamble recognized a role for the PDP apart from communicating label specifics necessary for safe and effective use. For example, where more than 60 percent of the surface area available to bear labeling is needed to present Drug Facts labeling, a company can use the modified Drug Facts format. "This formula is consistent with the idea that 40 percent of available labeling space is generally reserved for the UPC symbol and PDP." 64 Fed. Reg. 13254, 13267 (March 17, 1999). We see no reason to change that basic approach now and to risk further unnecessary label requirements on the PDP.

At the same time, we recognize the current statement of identity regulation does not require inclusion of all of the active ingredients in combination products on the PDP when the combination has no established name. Therefore, we agree with the agency that this should change for internal analgesics and that active ingredients in combination products with an internal analgesic should be included on the PDP. Many firms have already relabeled their products along the lines FDA suggests, but not necessarily with the one-quarter ratio the agency proposes.

(b) Products that have relabeled principal display panels to follow the "(NSAID)" highlighting discussion in FDA's June 2005 letters to NSAID NDA holders should not have to relabel to match the highlighting of the proposed rule. Under the proposed rule, for aspirin and other NSAIDs, the name of the active ingredient and the acronym "(NSAID") are to appear highlighted or in bold type. In contrast, FDA's June 2005 label template to NDA holders of non-aspirin NSAID products discussed using the acronym "(NSAID)" in fluorescent or color contrast or bold type – i.e., there was no discussion of highlighting the active ingredient name itself. Since these products already carry revised labeling on the PDP, we request that they not have to change again to highlight an additional word.

(c) The same points that apply to the ingredient ratio proposal also apply to the "see new warnings information" flag. In addition, the flagging requirements would benefit from further changes. As with the active ingredient-to-brand name one-quarter ratio proposal discussed above, we do not believe a requirement that the proposed "see new warnings information" statement on the PDP be in a size one-quarter that of the brand name is necessary or justified. In addition, we also ask whether or not FDA's proposal that the "see new warnings information" flag be in lines generally parallel to the base on which the package rests is more restrictive than necessary. The point of flagging the label to "see new warnings information" is to drive consumers' attention to the fact that there is new information they should read. As proposed, the generally parallel alignment requirement might or might not advance that goal any differently than other alternatives. Allowing

manufacturers the flexibility to implement that requirement as best fits their packages can similarly advance the goals of visibility and recognition. For example, just as the marketplace operates today, color, 45° angles with a corner placement, or other alternatives could be just as effective, if not more so, in attracting attention. The same flag placement on all products could also have the unintended impact of visual fatigue if it is seemingly so ubiquitous that consumers are indifferent to it. Three examples of the flexible approach, left to the manufacturer's discretion, are appended.

We would note that we do not in any way mean to suggest that allowing flexibility would limit FDA's ability to act against companies who attempt to skirt the intent of flagging. As with all label requirements, a flagging statement must meet the test of the law. It must be "prominently placed thereon with such conspicuousness ... and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions or purchase and use." See Food, Drug, and Cosmetic Act section 502(c), 21 U.S.C. 352(c).

(d) Clarification is needed on the timing and wording of the "See new warnings information" flag. The agency proposes that the "see new warnings information" flag on the PDP be included for one year after the effective date of the final rule or for one year after relabeling prior to the effective date. The association agrees with the concept of a PDP flag. Indeed, we have long had a voluntary program to flag the label when changes in labeling occur. In it, we suggest six months to one year. In the past, the agency has noted and commented favorably on this voluntary program.[1] We raise the question of timing simply to ask if one year is optimal. If the core intent is to draw consumer attention to the new information, a shorter time period, such as six or nine months, could have a similar impact. Our question is driven by a concern around other label changes that may be still to come – be they generated by other required label statements FDA is working on, or voluntary label or formulation changes. Depending on the timing of these changes, a "See new ..." flag could wind up being seemingly perpetual, thus risking fatigue.

Similarly, if a company went ahead voluntarily with label modifications now, as FDA encourages, and language of final rule is modified even slightly, the "see new

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[1] FDA noted, for example, that "the Proprietary Association [CHPA's former name] initiated a '*flag the label*' program . . . to alert consumers to significant changes in the ingredients or labeling of an OTC drug product. This 'flag the label' program informs consumers of changes in indications, dosages, active ingredients, directions, warnings, contraindications, or any other significant new information by using an attention-getting visual device (a flag) on the label. * * * The agency commends the program and encourages its continuation." 53 Fed. Reg. 30522, 30526 and 30530 (August 12, 1988).

warnings information" flag could wind up running for the voluntary year, and then re-running for yet another year once re-labeling was complete.

If the agency keeps, as proposed, the one year requirement for the "See new warnings information" flag, we would suggest the agency consider shortening the requirement or providing an exemption for products that have already carried a flag for the same label concepts where/if the final rule modifies the language but does not modify the underlying concept.

We also question if "See new warnings information" is the optimal language, as opposed to other alternative, attention-getting statements ("See new label," "See new information," "New label alert," "New label warning," etc.). If there are other label changes apart from warnings in addition to FDA's proposed new warnings, a company would be faced with carrying two flags at the same time – one for the new warnings, and another for the non-warning information. We suggest that FDA either allow firms flexibility in the wording of the attention-getting statement or, in the alternative, allow companies to add words to the statement to avoid having to carry two flags at once.

2. Drug Facts and other comments or clarifications.

(a) The proposed rule would benefit from clarification on highlighting ingredients. In 2001 and 2002, a number of CHPA members voluntarily changed labels to add a warning, "do not use with other medicines containing acetaminophen", outside of the Drug Facts label for products containing the ingredient. Some member companies also added a more explicit overdose warning within Drug Facts for acetaminophen-containing products. This included different variations of: "**Overdose warning:** Taking more than the recommended dose can cause serious health problems" and "**do not take more than directed** (see overdose warning)." Finally, in some instances, firms have highlighted the active ingredient and purpose section of the label for acetaminophen-containing products. It is clear that FDA's proposed new warnings obviate the need for the two voluntary warnings. However, what is the agency's intent regarding voluntary use of highlighting of the active ingredient and purpose section to draw attention to the presence of acetaminophen? We would appreciate clarification on this subject.

(b) Allowing flexibility to consolidate warnings in the "Ask a doctor" series could allow more efficient use of label space. To save a modest amount of label space, we recommend that FDA allow firms the flexibility to combine warnings under the "Ask a doctor or pharmacist before use if you are" section to alternatively use the heading "Ask a doctor or pharmacist before use if you are taking", and delete "taking" as the first word in the series of warnings that follow. This would allow firms to the option to communicate the same information, but save repetition of the word "taking" in a string series of warnings. In other words, it would follow the logic and model of bulleted warnings in general.

(c) NDAd products labeled only for children under 12 should not have to change the statement under directions re: adult use if they have already changed to a substantively similar statement. Under the proposed rule, products labeled only for children under 12 years of age would include a statement under the "Directions" heading that "this product does not contain directions or warnings for adult use" in bold type. In contrast, FDA's June 2005 label template to NDA holders of NSAID products discussed use of the statement "this product does not contain directions or *complete* warnings for adult use" [emphasis added]. Since NDAd NSAID products already carry the 'doesn't contain adult use directions' statement, we request that companies be given the option to include the word "complete" in this statement. This would remove the need for companies to re-label this portion of the label if they have already done so.

3. Conclusion.

To reiterate, the association believes the proposed ingredient-to-brand name and flag-to-brand name ratio requirements are unnecessary and not warranted. FDA's proposal for a flag to "see new warnings information" would benefit from greater flexibility and modest clarifications. Modest clarifications or changes would be useful in the new warnings proposed for the Drug Facts label concerning the highlighting of ingredients, consolidating warnings in the "ask a doctor" series, and on the adult use statement in children's products.

We appreciate the opportunity to submit these comments.

Respectfully submitted,

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Attachment: Alternative flag illustrations

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analgesic-comment507/dcs

Appendix to comments
Consumer Healthcare Products Association
Re: Docket No. 1977N-0094L

For illustration only. Not all elements are to scale.

(1) Flag as proposed by FDA:

(2) Alternative placement:

(3) Alternative wording: