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CITIZEN PETITION

The Consumer Healthcare Products Association ("CHPA") submits this petition under Sections 502, 503, 505, and 701 of the Federal Food, Drug, and Cosmetic Act ("FDCA") and 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs extend for two years the implementation deadlines in FDA's final rule on over-the-counter drug labeling.¹ CHPA represents the over-the-counter drug and dietary supplement industries. Its members account for over 90 per cent of the volume of OTC drugs products sold at retail in the United States. CHPA members therefore have a vital stake in the proper implementation of the new rule.

Companies have been making good faith efforts to comply with the final rule, and for a majority of products the rule as written will fit. However, for an

¹ 64 Fed. Reg. 13254 (March 17, 1999); corrected by 64 Fed. Reg. 18571 (Apr. 15, 1999).

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important minority of products, key questions regarding the new labeling requirements remain unanswered and are preventing companies from beginning conversion of existing product labels into the new format and beginning production of revised labeling. In some cases, such as columns and type size, industry raised the issues as far back as its comments on the proposed rule. Immediately following publication of the final rule, industry again raised these and other questions with FDA, and has over the past six months been engaged in a constructive dialogue with the agency. Nevertheless the issues remain unresolved.

The two-year extension requested in this petition is needed to restore the implementation time that has already been lost and take account of the additional time that will be required to discuss and resolve the many issues still pending. The currently open implementation issues include the use of columns, protection of trade dress, the exemption process, the use of type smaller than 6 points for certain small packages, the treatment of single use and other convenience packages, and the regulatory and other ramifications of extended text labeling (such as foldouts, risers, etc.). Of these, only the first two (columns and trade dress) have been the subject of extensive discussion, although even these have not yet been resolved. There has been some basic guidance from the agency on exemption petitions, but further elaboration is needed, and to date the necessary discussion between FDA and industry has not occurred. On the remainder of the issues, substantive discussions have yet to take place, much less to reach resolution.

It has become clear over the course of the feedback meetings held over the past six months that implementation of the final rule is far more complex than was

envisioned before its publication, even by CHPA and others who had been supportive of the rulemaking in general. In addition, new elements were included in the final rule that were not present in the proposed rule, such as placement of toll-free numbers and use of “Drug Facts Continued” labeling. The number and difficulty of the issues identified in several feedback meetings in the past six months indicates that at least another six months to one year will be needed simply to address and resolve the remaining issues, not including possible rulemaking to amend the final rule to reflect FDA resolution of certain issues. And as discussed below (see pp. 6 and 13), if a company ultimately determines that it must reconfigure its current packaging, significant lead times (in some instances in excess of 1 year) associated with package redesign and the installation and validation of new packaging equipment will be needed following resolution of the implementation issues recited in this petition.

A. Action Requested

The final OTC labeling rule generally provides a two-year implementation period for currently marketed products to comply with the new requirements. CHPA requests that this deadline be extended by two years, with a corresponding increase for low volume products. CHPA also requests that the new rule not apply to any product until some time after FDA has provided final clarification of the rules with which products must comply. For example, the rule should not apply to products with drug marketing applications approved after May 16, 1999 or to products with monographs finalized after May 16, 1999 until FDA resolves currently open implementation issues and companies are given sufficient time to incorporate FDA’s clarification into the label; for the monograph products, this would mean that the rule should not be effective sooner than two years after resolution of the issues.

Note that CHPA is not requesting an extension of the “drop dead” deadlines in FDA’s implementation plan (*i.e.*, the deadlines that apply six years out). Such long-term deadlines presumably will provide sufficient time without modification for FDA to issue further guidance and companies to adopt conforming labeling.

Pursuant to CHPA’s requested actions, the implementation deadlines for particular categories of marketed OTC drug products would run as follows (changes from the implementation chart in the corrected final rule are underscored):

Products	Time Periods
Single entity and combination products subject to drug marketing applications approved before May 16, 1999.	Within <u>4 years</u> (or within <u>5 years</u> if annual sales of the product are less than \$25,000).
Single entity and combination products subject to drug marketing applications approved on or after May 16, 1999.	Immediately upon approval of the application, <u>but in no event less than 2 years after resolution of the open implementation issues identified in this petition, as reflected in correspondence between CHPA and FDA acknowledging resolution of the issues as of a specified date.</u>
Single entity products subject to an OTC drug monograph finalized before May 16, 1999.	Within <u>4 years</u> (or within <u>5 years</u> if annual sales of the product are less than \$25,000).
Single entity products subject to an OTC drug monograph finalized on or after May 16, 1999.	Within the period specified in the final monograph, <u>but in no event less than 2 years after resolution of the open implementation issues identified in this petition, as reflected in correspondence between CHPA and FDA acknowledging resolution of the issues as of a specified date.</u> However, if a monograph has not been finalized as of <u>May 16, 2003</u> , then the product must comply as of the first major labeling revision after <u>May 16, 2003</u> or within 6 years, whichever occurs first.

<p>Combination products subject to an OTC drug monograph or monographs in which all applicable monographs were finalized before May 16, 1999.</p>	<p>Within <u>4 years</u> (or within <u>5 years</u> if annual sales of the product are less than \$25,000).</p>
<p>Combination products subject to an OTC drug monograph or monographs in which at least one applicable monograph was finalized before May 16, 1999 and at least one applicable monograph was finalized on or after May 16, 1999.</p>	<p>Within the period specified in the last applicable monograph to be finalized, or within <u>4 years</u> (or <u>5 years</u> if annual sales of the product are less than \$25,000), whichever occurs first. <u>However, in no event less than 2 years after resolution of the open implementation issues identified in this petition, as reflected in correspondence between CHPA and FDA acknowledging resolution of the issues as of a specified date.</u></p>
<p>Combination products subject to an OTC drug monograph or monographs in which all applicable monographs are finalized on or after May 16, 1999.</p>	<p>Within the period specified in the last applicable monograph to be finalized, <u>but in no event less than 2 years after resolution of the open implementation issues identified in this petition, as reflected in correspondence between CHPA and FDA acknowledging resolution of the issues as of a specified date.</u> However, if the last monograph is not finalized as of <u>May 16, 2003</u>, then the product must comply as of the first major labeling revision after <u>May 16, 2003</u> or within 6 years, whichever occurs first.</p>
<p>All other single entity and combination OTC drug products (e.g., products in the OTC Drug Review that are not yet the subject of proposed OTC drug monographs).</p>	<p>If a monograph has not been finalized as of <u>May 16, 2003</u>, then the product must comply as of the first major labeling revision after <u>May 16, 2003</u> or within 6 years, whichever occurs first.</p>

B. Statement of Grounds

Introduction

The final rule on OTC label format and content is the most far reaching and complicated regulation ever issued for OTC products, affecting the packaging and labeling of every shelf-keeping unit (SKU) of all OTC products currently marketed and

in the product development pipeline. This creates unique demands on company resources, which have never before been encountered. Compounding the complexity and magnitude of the rule are the open issues that still surround the implementation of the new labeling requirements. As stated above, the majority of products will fit the final rule. However, for a small but important number of products, the unresolved issues are quite significant, and have prevented companies from beginning the redesign and production of new labeling for the affected products. And as discussed below (see p. 13), there are significant lead times, sometimes in excess of one year, associated with package redesign, as well as purchase, installation, and validation of new packaging equipment. Companies cannot be expected to proceed with new labeling that might subsequently be deemed non-compliant. Thus, as an operational and practical matter, companies must wait for FDA to clarify key details regarding implementation of the new labeling format, and then, under the current deadlines, attempt to produce and implement new labeling by May 16, 2001.

The end result is that companies will not have two years to produce and phase in new labeling for the affected products, as originally provided for in the final rule. Rather, companies will face a considerably reduced implementation period. Over six months of the initial implementation period has already been lost, and the compliance clock continues to tick without the final clarification from FDA that industry needs to move forward. If the existing deadlines are not extended, companies will either have to seek exemptions or deferrals from FDA or discard stores of existing labeling stock that will become unusable when companies have to make a rapid transition to new labeling. In some cases, companies may have to discontinue product

lines altogether. In any event there would be a significant waste of industry and agency resources.

I. The Implementation Issues that Remain Unresolved are Significant and Prevent the Production of New Labeling.

Critical issues concerning the label formatting under the new rule are unresolved. These open issues include the use of a column format to present the information required by the rule, the use of light printing on a dark background in accordance with a product's distinctive trade dress, the exemption process including treatment of confidential information, smaller font size for certain small packages, and numerous other details concerning package layout and special packaging formats (*e.g.*, single use and other convenience packages, extended text labeling). Because these matters are central to the design and production of new labeling, companies cannot proceed with implementation of the rule for the affected products until they receive further guidance.

The issues of the use of columns and the protection of trade dress illustrate the complexity of the rule and the dilemma companies face. Column formatting affects how much available label space the new required information will occupy. Industry has explained to FDA that columns can be used to incorporate the "Drug Facts" information and required headings and subheadings in a more readable and efficient manner. Column formatting is generally regarded as a factor that enhances readability, and FDA's own regulations for nutrition labeling provide for use of column display as a preferred format. 21 CFR § 101.9 (d).

However, FDA has questioned whether the formatting specifications in the final rule (*e.g.*, the required bar lines and hairlines) technically preclude the use of

columns. This issue of whether columns may be used is not new. CHPA referred to columns in the 1997 comments it submitted to FDA on the proposed OTC labeling rule, as did other commentators. Nevertheless, no resolution has yet been reached. As Dr. Charles J. Ganley, Director of the Division of Over-the-Counter Drug Products, stated in an August 9, 1999 letter to CHPA, “[t]he columns format issue is currently under discussion within the agency and will be discussed in a separate communication.” (Attached as Exhibit 1). CHPA has subsequently received some indication from Dr. Ganley and others at FDA that the agency may provide some accommodation on the column issue, but the specifics are unclear, and the issue appears to remain under review at the agency. FDA’s ultimate position will determine how companies will integrate the labeling on product packaging, whether new packaging must be developed, and whether companies must seek exemptions from the new requirements for certain products.

The issue of using light printing on a dark background in accordance with a product’s trade dress is similarly unresolved. Certain products currently use a distinctive trade dress with light printing on a dark background. The new labeling information can be incorporated into such a color and design scheme to present information in a clear and readable manner. However, the technical formatting requirements of the final rule may preclude use of light printing on a dark field. As Dr. Ganley stated in his August 9, 1999 letter, “[t]rade dress and special package exemptions will require further detailed discussions with industry.” Industry has since made a presentation to FDA on the trade dress issue, and understands that FDA is actively considering the issue. No final resolution has been issued. If light printing on

a dark background is not permitted, then companies with affected products may have to design entirely new trade dress.

These issues of the use of columns and light-on-dark printing are of particular importance to the industry. Permitting columns would enable companies to make more efficient use of label space while making information more readable and preserving helpful white space. Use of columns would also advance FDA's goal of maximizing the number of OTC labels that conform to the standardized appearance, since the space saved by columns would eliminate the need for companies to use alternative packaging such as wraparound labels. If columns cannot be used, companies will have to redesign and expand the available label space of certain products so that the new required information can be included along with other information that must appear on packaging (*e.g.*, UPC code, name/place of manufacturer, lot number, expiration date, tamper-evident statements, required disclaimers, voluntary warnings, etc.). Even if the existing physical packaging could be preserved for other products, industry has shown that the Drug Facts information panel can be made more consumer friendly if the required text were broken up into columns rather than presented in long lines of text. Use of column formatting has been a standard industry labeling practice for decades.

The use of light printing on a dark background is equally important, even though it does not affect the printable space or physical composition of the package. The use of color is integral to a product's distinctive trade dress, and helps consumers readily identify the product. Permitting companies to use light printing on a dark background for the new Drug Facts information panel would allow companies to

present the panel in a manner that is consistent with current trade dress and design. As long as the Drug Facts panel can be made just as conspicuous and readable with light printing on dark as with dark printing on light, there seems no compelling justification for forcing companies to redesign their current trade dress in order to incorporate the new labeling requirements.

Other outstanding issues further compound the compliance problem for industry. For example, another key issue on which there has been only limited discussion with the agency involves the use of a type size smaller than 6 points. FDA has only recently, at the September 17 feedback meeting, suggested that there may be circumstances under which it might permit use of less than 6 point type in the OTC label. Further dialogue between FDA and industry on this issue is crucial.

Proper resolution of these and other key implementation issues (the exemption process, treatment of single use and other convenience packages, etc.) is critical to realizing the anticipated benefits of the final rule and avoiding the imposition of unnecessary burdens on industry. As such, it has been entirely appropriate for FDA to engage in an ongoing discussion with industry before formulating final policy. While that process plays itself out, however, industry remains unable to implement the new requirements. Put simply, companies cannot finalize new labeling for many SKUs until the rules are set with which the labeling must comply.

II. Industry has Been Proactive in Identifying and Attempting to Resolve the Currently Outstanding Implementation Issues.

It is important to note that industry has been proactive in bringing unresolved implementation issues to FDA's attention and working with FDA to reach appropriate solutions. Industry has diligently "test driven" the final rule to determine

key problem areas that were either not addressed or not adequately explained in the final rule. Because of the complexity of the rule's typographical and other provisions, this process is still ongoing. Nevertheless, CHPA sent a preliminary memorandum to FDA with questions about the final rule only two days after the rule was published in the Federal Register on March 17, 1999. CHPA and FDA have over the past six months engaged in an extended exchange of correspondence and information, and met on several occasions to share views, including most recently on September 17. (A chronology of CHPA's contacts with FDA regarding implementation of the new rule, along with supporting documentation, is attached as Exhibit 2.) Thus, the need for an extension of the current implementation deadlines does not reflect any lack of diligence on the part of industry, but rather arises directly from the uncertainty that continues to surround certain key aspects of the rule.

III. Extending the Current Deadlines by Two Years will Allow Companies to Phase in Conforming Labeling in the Manner Originally Contemplated by FDA.

FDA's entire economic analysis of the impacts of the final rule was based on the assumption that companies would have two years in which to adopt new labeling for currently marketed products. As FDA explained, its implementation plan was designed to "provide[] manufacturers with sufficient time to design and print new labeling and to deplete existing stock." 64 Fed. Reg. at 13272. Based on the assumption that manufacturers would generally be able to use up old labeling and transition to new labeling within two years, FDA was able to state that its implementation plan was intended to "minimize the economic burden on the industry while providing consumers with the benefit of more readable and understandable OTC drug product labeling at the earliest feasible date." 64 Fed. Reg. at 13272. These

assumptions will only remain valid if FDA extends the current implementation deadlines to ensure that manufacturers really do have two years to design and print new labeling and deplete existing stock.²

Without an extension to restore the implementation time that has been lost while FDA addresses uncertainty about key aspects of the rule, the costs and benefits of the rule will vary considerably from FDA's analysis. This can be seen from even a cursory review of what a company would face absent an extension. No company should be expected to design, print, and begin to use new labeling that employed columns "at risk," without knowing whether it would be deemed compliant with the rule. A company could await final resolution of the rule's requirements from FDA and then design and print new labeling. However, depending upon when final clarification is issued, companies would not be able to deplete existing labeling stock for some products, and would simply have to discard old inventory and switch to new.

Alternatively, a company could seek a deferral or exemption from FDA. The resulting burden on the agency would depend on how many requests it had to review. A company could not proceed on a new label until it received an FDA response to its petition, with the response time unknown. To date, FDA has received and acted on two exemption petitions, with responses issued in three months and one month, respectively. Whatever option companies pursue, both industry and FDA will have to

² Even if no outstanding implementation issues remained, FDA's two-year deadline would have been overly aggressive. In comments submitted on the proposed rule, CHPA asked for a three-year implementation period. CHPA's and FDA's economic analyses are widely different, and CHPA believes that the industry estimates provide a more realistic projection of costs unanticipated by the agency.

devote significant resources to the compressed implementation of the rule, and substantial economic waste will result.

FDA can help to avoid such costs by ensuring that companies will have two years to implement the new rule for currently marketed products following final clarification of the rule's requirements. CHPA is not in a position to predict when that final clarification will come. Nonetheless, a two-year extension seems appropriate given that over six months have already elapsed since publication of the final rule.

It is important to recognize that the route a company takes on labeling is dependent on FDA resolution of the variety of issues raised during the course of the ongoing feedback meetings.³ For example, depending on FDA responses, a company may conclude to use alternative packaging such as wraparound labels or risers, which require purchase of new labeling equipment and in-house validation. Multiple products and SKUs of different sizes and configurations would mean purchase of additional labeling machinery and validation. This process of purchasing machinery and ensuring validation could take 6 months to a year. With many companies potentially facing the same labeling issues, there will also be competition for labeling equipment from a limited number of suppliers, further complicating compliance timelines.

Similar problems arise regarding graphic design, particularly for smaller companies. Companies use both internal and external graphic designers. Competition for the time of external graphic designers can be expected once FDA has resolved the label issues, creating further potential delays in creating new labeling.

³ This petition does not seek specific action on any of the substantive issues, and industry reserves all of its rights in this regard.

Finally, the rule's effective date as applied to OTC categories where final monographs are expected soon is especially troublesome. Under the rule, the effective date for compliance is the effective date of the final monograph. According to FDA's semi-annual regulatory agenda, final monographs are expected in the near future for skin protectants, phenylpropanolamine, and parts of the internal analgesics rule, among others. Companies who manufacture these products cannot plan for new labels until FDA has provided resolution on the key issues described above. They require a reasonable lead time to adopt appropriate labeling following adoption of a final monograph and the issuance of further clarification of the labeling rule.

IV. Public Health Considerations Do Not Justify a More Expedited Implementation Schedule.

FDA adopted new standardized OTC labeling requirements with the stated justification of enabling consumers "to better read and understand the information presented" and "apply this information to the safe and effective use of OTC drug products." 64 Fed. Reg. at 13255. Notably, FDA did not cite any data suggesting that current labeling has created a safety problem or other public health concern. Thus, although improving OTC drug labeling is a laudable goal, there are simply no public health considerations at issue here to justify the costs that would be associated with requiring industry (and FDA) to implement the new rule on a compressed timetable.

Moreover, granting the extension will not affect products for which companies are already adopting new labeling. For example, companies have already begun to move forward to make changes to the labels of products where the final rule as written will fit without need for resolution of the issues recited above, *e.g.*, for OTC single ingredient products subject to a final monograph that are in full size packaging.

In some cases, the companies even expect to have product with the new label in the marketplace ahead of the current May 16, 2001 effective date. Thus, while the extension requested here is crucial for many products and companies, it will not delay implementation for the majority of the OTC market. Finally, the FDA's current six-year "drop dead" deadline would remain unchanged.

Conclusion

For the reasons set forth in this petition, FDA should extend the implementation deadlines in the final OTC labeling rule by two years.

C. Environmental Impact

The actions requested herein are subject to categorical exclusion under 21 C.F.R. §§ 25.30 & 25.31.

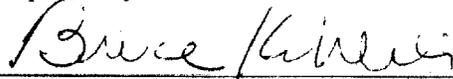
D. Economic Impact

An economic impact statement will be submitted at the request of the Commissioner.

E. Certification

The undersigned certifies that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



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Attachments:

- Exhibit 1—August 9, 1999 letter from Charles J. Ganley, M.D., FDA, to CHPA
- Exhibit 2—Chronology of CHPA contacts with FDA re implementation of the final rule, with supporting documentation.

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