

March 22, 2016

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

Docket No. FDA-2015-N-1260

Dear Sir or Madam,

On behalf of the Consumer Healthcare Products Association (CHPA)¹, enclosed herein are comments on “Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients under Consideration for Inclusion in an Over-the-Counter Monograph”, published as a proposed rule.² CHPA and our member companies have an interest, experience and expertise in over-the-counter (OTC) co-packaged drugs and appreciate this opportunity to comment on the proposed rule. Our comments are divided into general comments and section-specific comments.

General Comments

In general, CHPA supports FDA’s intent to harmonize the requirements for Rx and OTC products and make them consistent with long-standing Agency policy. However, nonprescription drugs and prescription drugs are marketed and sold in distinct and separate ways, and carry with them specific benefits and risks. Unlike prescription drugs, OTC drugs are typically purchased by a consumer without the involvement of a healthcare professional. For that reason, FDA created Drug Facts to ensure that consumers could readily access important information about an OTC drug such as active ingredients, directions for use and warnings, enabling appropriate self-selection. We are concerned that FDA’s proposed definition of the term “co-packaged drug” could cause significant confusion within industry and among consumers regarding what OTC products are covered by the proposed requirements, given FDA’s proposed definition of “co-packaged” is substantially different from that used every day by consumers and in commerce.

We do not agree with FDA’s conclusion that the act of packaging two drug products together inherently means that the two drug products are intended to be used together absent specific labeling language to the contrary. Many OTC products that are packaged together are not intended to be used together, and this is well-recognized by consumers even if such products do not bear an alternative explanation in the packaging such as “convenience” or “value pack.” In

¹ The Consumer Healthcare Products Association (CHPA) is the 135-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products.

² **Federal Register**, Vol 80, No. 246, December 23, 2015, pp. 79776-79795.

addition, while FDA explains that OTC drugs packaged together and labeled as “value”, “travel”, etc. would be excluded from the scope of this rule³, these products are literally “co-packaged”, and hence, the proposed use of the term “co-packaged drug” to describe just a limited category of drug products packaged together, but not other drug products also packaged together, has significant potential to generate confusion among those who handle the many OTC products sold together, including manufacturers, retailers and consumers. Finally, under FDA’s proposed presumption that drug products packaged together are intended to be used together, we are concerned that each example term that could be used in labeling to overcome this presumption (e.g., “value,” “travel”) must be cited in the regulation in order for the product to be exempt. While we can generate a list of terms used today, such as family pack, bonus pack, convenience pack, free sample, first aid, there could be many other terms used in the future that are also acceptable but not clearly addressed in the preamble.

To address these concerns, we request that FDA consider using a more specific term or definition to describe the subset of co-packaged drug products that would be subject to the proposed requirements, so that interested parties will not be confused about the scope of the term “co-packaged drug” when used in other contexts. This is explained in further detail below. We also request that FDA explicitly state in its regulatory definitions that drug products that are packaged together are only subject to the rule’s requirements if their packaging or labeling affirmatively indicates that the products are intended to be used together.

Overall, while we wish to support FDA’s effort here, the term “co-packaged” has multiple meanings outside of the regulatory environment and we are concerned that this proposed rule, unless much more clearly clarified regarding exemptions, may have unintended consequences and cause regulatory uncertainty for manufacturers and retailers.

Specific Comments

Section II.B. Advantages and Disadvantages of Fixed-Combination and Co-Packaged Drugs

Day/night cough/cold products sold together are not currently described in the monograph for OTC cough-cold drug products, nor would we support including them in the monograph. These products have at least some different ingredients and thus different labeling to reflect the use of each product. We disagree that this presentation meets FDA’s proposed definition of co-packaged drug. This presentation is done for consumer convenience and value and should be exempt from the rule. Relatedly, the cough/cold combination monograph did not consider the possibility of co-packaged drugs, only the combination of multiple ingredients into a common dosage form. This is why the combination rule includes specific labeling to be used if specific actives are combined together in one dosage form. Therefore, FDA should not be using the combination rule as the basis for a co-packaged product.

Section III.A.4. Co-Packaged Drug

Consumers understand that two OTC drug products that may be packaged together or sold separately are not intended to be used together. FDA’s focus of the rule should be co-packaged drugs intended to be used concomitantly and labeled to be used as such. While FDA proposes to exclude OTC drugs sold together and labeled as “value”, “travel”, etc. from this rule, these

³See 80 FR 79781

products are literally “co-packaged”, and hence, the proposed definition has significant potential to generate confusion among those who handle the many OTC products sold together, including, manufacturers, retailers and consumers.

Consumers routinely see products with samples affixed, or adult/child versions of a product sold together. These products, whether labeled “convenience” or “value pack” or not, are clearly not intended to be used together, nor is this an implied claim. Simply shrink-wrapping a dentifrice and a mouth rinse together (each with clear labeling on intended use) should not deem these products as a new drug without a label for convenience or value. Is such an OTC product missing a term such as “convenience” at risk for a recall? We disagree that shrink wrapping absent labeling such as “convenience” or “value pack” is an implied claim that the products are intended to use used together.

In an effort to increase clarity, CHPA proposes that the rule clarify the definition of a co-packaged drug to be:

Co-packaged drug is a product that contains two or more separate drugs in their final dosage forms that are intended to be used together at the same time for a common or related therapeutic purpose, labeled as such and that are contained in a single package or unit.

Should FDA not agree with the industry-proposed definition, the industry requests in the preamble to the final rule that FDA provide clarity on the types of labeling that render products not subject to the final rule and confirmation that products bearing the intent of the examples are not subject to the requirements of the final rule. The table in Attachment 1 summarizes examples of interpretation of FDA’s proposed rule but it is impossible to generate a comprehensive list of terms today to assure that all exempt products will be appropriately labeled. The rule should reflect such flexibility since there could be many other terms used in the future that are also acceptable.

Further complicating attempts to define terms for labeling exempt products are other regulations or guidelines related to their use. For example, the FTC has a number of regulations regarding multiunit packages, variety packages, combinations packages and introductory offers. In addition, retailers and manufacturers may restrict the length of time certain labeling, such as “value pack”, may be on a product. If manufacturers must add certain labeling terms such as “value” to ensure that FDA doesn’t consider two drug products packaged together to be intended for use together, then those labeling terms could potentially trigger requirements imposed by agencies other than FDA related to the use of the terms.

We disagree that a dietary supplement co-packaged with a drug means the dietary supplement has a therapeutic purpose and is therefore a drug. The dietary supplement could be a sample or could be a value or convenience pack (e.g., a cough/cold medicine plus a calcium supplement; an antacid plus a probiotic supplement; a pain medicine plus a bonus pack of multivitamins). The same rules that would apply to a co-packaged OTC drug would apply in this case.

Section III.A.9. Natural Source Drug

We agree with the proposed definition, the examples cited and that they do not involve the intentional combining of active ingredients. Hence, we also agree that they should not be subject to this proposed rule.

Section III.C.3. Requirements of the Proposed Rule. Combinations in which Active Ingredients are Directed at Different Signs or Symptoms of a Disease or Condition

We agree with FDA that in cases where OTC drug monographs describe acceptable combinations of active ingredients directed at different symptoms arising from a single condition, such as a cold, factorial design clinical studies are generally not needed to demonstrate the contribution of each active ingredient. Each active ingredient would be expected to have its usual, independent effect on a symptom. This section would benefit from an example of where a factorial design clinical study may be needed. This section would also benefit from clarification of "OTC drug monograph" to include all monographs in all stages of development, e.g. ANPR, TFM, final monograph.

We are available for further discussion of these comments and look forward to FDA's response.

Respectfully submitted,

A handwritten signature in blue ink that reads "Barbara A. Kochanowski". The signature is written in a cursive style.

Barbara A. Kochanowski, Ph.D.
Vice President, Regulatory & Scientific Affairs
202-429-3530

Attachment 1

<u>Examples of Labeling of Co-Packaged Drugs not Subject to the Requirements of the Proposed Rule (additional terms are acceptable)</u>	
<i>Label</i>	<i>Example</i>
Convenience Pack or Convenience Kit	Same or different products in shrink-wrapping or otherwise packaged together
Value Pack	Same or different products in shrink-wrapping or otherwise packaged together
Travel Kit	OTC drugs are packaged together for convenience or value not intended to be used together for a common or related therapeutic purpose
Special Value	Same or different products in shrink-wrapping or otherwise packaged together
Products not intended to be used together	OTC drugs are packaged together for convenience or value not intended to be used together
Family Pack	Different products in shrink-wrapping or otherwise packaged together for multiple age groups
Bonus Pack	Same or different products in shrink-wrapping or otherwise packaged together
Free Sample	Same or different products in shrink-wrapping or otherwise packaged together
First Aid Kit	Different products in shrink-wrapping or otherwise packaged together