

Kirkpatrick & Lockhart LLP

1800 Massachusetts Avenue, NW
Suite 200
Washington, DC 20036-1221
202.778.9000
www.kl.com

May 13, 2002

Gary L. Yingling
202.778.9124
Fax: 202.778.9100
gyingling@kl.com

Dockets Management Branch (HFA-3-5)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on FDA Notice of Partial Delay of OTC Drug Labeling Compliance Date for "Convenience Size" Drug Packages and Plan to Propose Rule: (Dockets No. 98N-0337, 96N-0420, 95N-0259, 90P-0201, and 01P-0207/Let-1)

Dear Sir/Madam:

On behalf of our client, Mechanical Servants, Inc., we provide the following comments which concern the Food and Drug Administration's ("FDA") recent decision to:

- (a) issue a proposal to modify the labeling format and content requirements rule for over-the-counter ("OTC") drug products ("Drug Facts Rule" or "Rule") for "convenience size" OTC drug packages; and
- (b) delay the Drug Facts Rule compliance date with respect to "convenience-size" OTC drug products.

See 66 Fed. Reg. 16,304 (April 5, 2002); Letter to James M. Nikrant from Steven Galson, Acting Director, FDA Center for Drug Evaluation and Research, January 18, 2002, Docket No. 01P-0207/Let 1.

Mechanical Servants is a Chicago-based drug relabeling company that specializes in packaging "convenience size" OTC drug products. It has been servicing the convenience industry since 1955, meeting the needs of consumers in hotels, airports, travel plazas, and cruise ships. In addition, Mechanical Servants provides convenience size products to convenience stores, and traditional drug, grocery, and mass merchandising locations. The availability of convenience size drug products satisfies both the instant need for use by consumers, as well the need for small drug packages that can be kept in purses or briefcases, or for future use during travel.

Like Lil' Drug Store Products, Inc. ("Lil' Drug Store"), the petitioner identified in Docket No 01P-0207 and the company that provided the impetus for FDA's current action, Mechanical Servants recognizes the important role that the convenience industry serves in meeting the needs of consumers who may be temporarily limited to shopping at a convenience store or non-

90P-0201

C 79

Dockets Management Branch
May 13, 2002
Page 2

drug store location. There are over 120,000 convenience stores in the United States, with over one billion dollars in sales generated by these stores in the health and beauty category alone. See Convenience Store News (CSNews.com). These sale statistics establish broad consumer reliance on such venues as a source for safe and effective health-related products.

However, Mechanical Servants does not agree with Lil' Drug Store's position that convenience store consumers require less drug product information at the point-of-purchase than those purchasing regular multiple-dose packages of OTC drugs. In fact, Mechanical Servants believes that there is a heightened need for adequate and complete directions for use because, as noted in the Lil' Drug Store petition, many of these consumers plan on using the drug product immediately upon purchase in order to relieve their symptoms. Hence, making the right choice at the point-of-purchase becomes critical.

As a result, Mechanical Servants cannot support Lil' Drug Store's proposed modification to the Rule. However, Mechanical Servants would support an FDA policy that limits the information that must appear on the "inner package" of a convenience size OTC drug product. Mechanical Servants intends to submit a citizen petition requesting that FDA acknowledge, through implementation of a guidance or policy statement, that the "inner package" labeling in most convenience size drug products can be limited to an identification of the proprietary name of the drug product, the lot number, and the expiration date where fully compliant labeling appears on the outer container of the retail package. The petition will also address the need for FDA to acknowledge and accept a "reverse guaranty" as a basis for exemption from certain liabilities under the Federal Food, Drug, and Cosmetic Act ("the Act"). Mechanical Servants' position on these matters is provided below.

I. The Outer Package of the "Convenience-Size" OTC Drug Product Should Comply with FDA's Format and Content Requirements for OTC Drug Products.

In its petition dated April 27, 2001, Lil' Drug Store asked FDA to allow truncated retail package labeling for "convenience size" OTC drug products.¹ Lil' Drug Store stated that allowance of the truncated retail package labeling should be conditioned upon a requirement that (a) fully compliant Drug Facts labeling appears in the internal packaging of the convenience size drug product, either through the use of package inserts or through inner package printing, and (b) the outer wrapper of the retail package is labeled with the following bolded statement:

¹ The petitioner proposed a definition of "convenience size" OTC drug products as packages sold to the public that contain one or two doses of OTC drug products. See Lil' Drug Store Citizen's Petition, No. 01P-0207. In FDA's notice announcing a partial delay of the Rule's compliance date for convenience size OTC drug products, FDA accepted this definition, but added a further qualification that, because of limited available labeling space, more than 60 percent of the labeling space would be required in order to meet the Rule's requirements. See 67 Fed. Reg. 16,304 at 16,306. Mechanical Servants generally agrees with the proposed definition of "convenience size" and would support its adoption.

Kirkpatrick & Lockhart LLP

Dockets Management Branch
May 13, 2002
Page 3

“Please read complete Drug Facts information inside prior to use.” See Lil’ Drug Store Citizen’s Petition, No. 01P-0207.

Lil’ Drug Store specifically petitioned for an outer package Drug Facts panel that abbreviates information appearing in the “warnings” and “other information” sections, and excludes the “directions” and “questions or comments” section. In proposing these modifications, Lil’ Drug Store reasons that certain Drug Facts labeling information is not necessary at the point-of-purchase for the consumer of convenience size drug products. For example, Lil’ Drug Store proposes the exclusion of warning information required under 21 C.F.R. § 201.66(c)(5)(iv). This section, which bears the heading, “Ask a doctor before use if you have . . .”, requires the listing of all preexisting conditions and symptoms for which the consumer should consult a doctor before using the product. Lil’ Drug Store states that it is not important for this information to appear on the outer wrapper of convenience size OTC drug products because negative side effects are unlikely to be associated with the low drug dosages delivered in these package sizes.

Mechanical Servants is unaware of any support for such a statement. FDA’s decision to allow the marketing of OTC drugs is largely premised on labeling that allows patients to self-medicate safely. Required warnings about preexisting conditions identify certain persons who are more susceptible to adverse effects when a particular OTC drug product is used. For example, persons with kidney disease are cautioned against using certain antacids without first consulting a doctor. See 21 C.F.R. Part 331. It is possible that use of even one or two doses of an antacid by such persons could seriously compromise their health. Thus, Mechanical Servants disagrees with Lil’ Drug Store’s rationale for excluding this drug labeling information. Further, a consumer would be greatly inconvenienced to discover, after purchasing the convenience-size drug package and reading the full Drug Facts labeling information inside the package, that he or she should refrain from use of the drug product.

Lil’ Drug Store also proposed the exclusion of warning information contained in 21 C.F.R. § 201.66(c)(6)(v). This warning section, which bears the heading “Ask a doctor or pharmacist before use if you are . . .” requires the listing of all drug-drug and drug-food interactions. Lil’ Drug Store states that it is not important for this warning information to appear on the outer wrapper of convenience size OTC drug products because “[t]here are generally no pharmacies located in the retail environment in which Convenience Size OTC Products are retailed.” See Lil’ Drug Store Citizen’s Petition. Mechanical Servants disagrees with this reasoning because it does not address the true purpose of the warning. In fact, Mechanical Servants believes that the absence of a doctor/pharmacist at locations where OTC drugs are sold heightens the necessity for interaction warning information on the outer retail packaging of drug products. As an example of the types of drug products that would bear such a warning, OTC night time sleep aid drugs should not be taken with tranquilizers or sedatives without first consulting a doctor. See 21 C.F.R. § 338.50(c)(4). It is possible that serious medical injury would result if the purchasing consumer used the OTC sleep aid in conjunction with tranquilizers

or sedatives. Clearly, the fact that a pharmacist or physician is not available for consultation is irrelevant to the importance of the required warning.²

If Lil' Drug Store's proposal was adopted, we would hope that the purchasing consumer who is using sedatives or tranquilizers will decide not to also use the sleep aid after reading the full Drug Facts labeling directions found inside the sleep aid packaging. In this case, at worst, Lil' Drug Store's proposal would result in an unhappy and inconvenienced consumer who purchased a product that could not be used.

Lil' Drug Store also proposes the exclusion of directions for use. Mechanical Servants would expect that consumers use this information to determine the dosage frequency and the time period for which relief from an ailment will be provided. A comparison of some pain relievers will show that some require dosing every four hours, while others require dosing every six to eight hours. A patient seeking a longer acting product may be disappointed to later find out that the product purchased requires dosing every four hours. This information is important to customer satisfaction and thus, Mechanical Servants believes this information should remain on the outer wrapper of the retail package.

In conclusion, while there may be a reasonable basis for allowing some drug information to appear in the inner package labeling only, Mechanical Servants believes that this matter must be carefully measured against FDA's intent in establishing the Drug Facts Rule. In the preamble to the final Drug Facts Rule, FDA stated that a standardized labeling format would significantly improve readability, help consumers locate and read important health and safety information, and allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product. See 64 Fed. Reg. 13, 254 (March 17, 1999). Truncating the outer package drug labeling information as proposed by Lil' Drug Store will certainly defeat these purposes.

II. Current Labeling Options Allow the OTC Convenience Drug Product Industry to Comply with the Drug Facts Rule

As Lil' Drug Store acknowledged in its petition, there are labeling options that allow OTC convenience drug products to comply with the Drug Facts Rule. In fact, Mechanical Servants has been working on developing such labeling for its customers for quite a while and plans on being in full compliance with the Drug Facts Rule by the primary implementation date of May 16, 2002. While there may be additional costs associated with such labeling, this reality has affected the entire OTC drug industry, not just the convenience size drug product sector. Further, although Mechanical Servants agrees with Lil' Drug Store's comment that increasing the outer package size to accommodate the information required under the Drug Facts Rule is impractical due to convenience store space limitations, use of a peel-away label option should

² We also note that there are many places where regular size OTC drug products are sold and neither a pharmacist or physician is immediately available for consultation (e.g., supermarkets, certain department stores).

Dockets Management Branch
May 13, 2002
Page 5

negate the need to resort to an increased package size in most circumstances. For your review, we attach a sample of the retail packaging Mechanical Servants plans to employ for its OTC convenience drug products.

Mechanical Servants believes that the peel-away label option better serves the purchaser of convenience size OTC drug products by allowing the purchaser to make an informed decision at the point-of-purchase. The benefits of purchasing a product that can be safely used by the consumer certainly outweigh the possible increase in cost associated with the peel-away labeling. In fact, the use of the proposed truncated version of the Drug Facts panel likely will increase the cost to a purchasing consumer who later finds out, from the full labeling inside the drug product, that the product should not be used. Moreover, as explained below, it may be possible to offset the additional labeling costs associated with the outer package of the retail package by limiting the labeling information that must appear on the drug product inner package.

III. The Inner Pouch of Convenience Size OTC Drug Product is Not Subject to Drug Labeling Information

The Drug Facts Rule applies only to the outside package or outer wrapper of the retail package. See 21 C.F.R. § 201.66. Therefore, where an outer wrapper exists, the Drug Facts Rule does not apply to drug labeling found inside the outer wrapper, including any inner package or pouch. Putting the Drug Facts Rule aside for a moment, we would like to address general drug labeling requirements, if any, associated with inner drug packaging. As FDA knows, it is not unusual for a drug product to have both inner packaging and outer packaging. Frequently, the inner packaging must bear drug "label" information, most of which duplicates what appears on the outer packaging.³ However, in some circumstances, it is not practical or necessary to require drug label information to appear on the inner packaging. For example, it is our understanding that drug label information is not required on the back lining of a blister pack card of drugs. This policy makes sense because label information is defaced when individual dosage units are removed from a blister pack card.

The problems associated with labeling blister pack cards also applies to most convenience size drug product inner packages. These inner packages, which are usually in

³ The Act defines the "label" as "a display of written, printed, or graphic matter upon the *immediate container* of any article. See 21 U.S.C. § 321(k) (emphasis added). At a minimum, the label must bear an active ingredients statement (section 502(e) of the Act), the name and address of the manufacturer, relabeler, or distributor (Section 502(0b)(1) of the Act), a net contents statement (section 502)(b)(2) of the Act), a lot number (21 C.F.R. § 201.18), and an expiration date (21 C.F.R. § 201.17). See FDA's comments on small container drug products 59 Fed. Reg. 43,386, 43,399 (August 23, 1994). Further, some drug products require additional labeling information on the "label" (e.g., the Reye's Syndrome warning for drug products containing salicylates (21 C.F.R. § 201.314).

Kirkpatrick & Lockhart LLP

Dockets Management Branch
May 13, 2002
Page 6

pouch form⁴, generally are just large enough to hold a single dose of an OTC drug product. A review of the attached Mechanical Servants sample presents a good example of the typical inner pouch size. These pouches usually do not have much more than eight square inches of labeling space. Thus, the required "label" information would be difficult to accommodate on a convenience size drug product inner pouch, particularly where a multi-active drug ingredient product is concerned. Even if all the required label information is provided on the inner packaging, the type size used is generally so small that questions about readability arise.⁵ Moreover, unlike the opening of an inner package that is in bottle form and has a lid, the tearing open of these inner pouches would result in the defacement of the "label" information.

Because it is impractical, and really unnecessary to require that convenience size OTC drug product inner pouches bear the drug label information, Mechanical Servants recommends that FDA acknowledge, through a guidance or policy statement, that only the convenience size drug product *outer* package must bear the drug "label" information.⁶

This policy would prevent the bizarre result that if the convenience size drug product inner package is a blister pack card, the label is located on the outer packaging, but if the inner package is in another form, such as a pouch, the label is located on the inner package. There is no concern that such a policy will raise safety issues. Most users of convenience size drug products use the drug products immediately upon purchase in order to self-treat symptoms.⁷ Thus, duplicative labeling merely increases costs to the consumer without increasing safety.

The Act does not provide for any specific drug labeling statements that must appear on an inner drug package where that package does not fit within the definition of "immediate

⁴ FDA's "CDER Data Standard Manual" describes a pouch as "a flexible container used to protect or hold one or more doses of a drug product. See CDER Data Element Number C-DRG-00907, revision date: July 26, 1999.

⁵ We recognize that, in the past, many convenience size inner pouches were labeled in a manner that may have allowed them to be made available for retail sale in the absence of an outer wrapper. However, it is questionable whether the consumer could actually read the required labeling information, which raises the issue of misbranding under 21 U.S.C. § 352(c) and 21 C.F.R. § 201.15(a)(6). Further, with the implementation of the Drug Facts Rule, retail sale of these pouches would be all but impossible due to label space limitations.

⁶ There are probably some that would suggest that the convenience size drug product inner pouch is the "immediate container." By "immediate container", we are referring to the portion of the packaging that must bear the drug "label" information." See 21 U.S.C. § 321(k). The Act does not define "immediate container." However, it is clear that the "immediate container" may not always be the inner packaging. For example, the Act specifically states that the definition of immediate container does not include "package liners." See 21 U.S.C. § 321(l). The back lining of a blister pack also appears to be excluded from the definition of "immediate container". We believe that the inner pouch of a convenience size drug product should also be excluded from the definition of "immediate container."

⁷ This matter was adequately addressed in the Lil' Drug Store citizen petition.

container.” See footnote 4. However, Mechanical Servants would recommend that the FDA guidance or policy statement on this matter require that the inner package of a convenience-size drug product to bear the proprietary name of the drug, the lot number, and the expiration date. Such labeling would be consistent with current industry practice in connection with the labeling of blister pack cards, and would allow for an effective recall if needed. While manufacturers may choose to add additional product information to the inner pouch, this should be a voluntary decision. Limiting the inner pouch labeling requirements associated with convenience size OTC drug products will minimize packaging costs and thus, address some of the economic concerns raised by Lil’ Drug Store.

Moreover, simplification of the labeling process will encourage drug manufactures to continue to assist in packaging convenience size drug products. For FDA’s information, it is not uncommon for the drug manufacturer to provide the inner packaging material to the convenience size drug products relabeler. If the full drug labeling information is readily available where it needs to be (i.e., the convenience size drug product outer package), the manufacturer of the inner pouches will be relieved of a burden which, hopefully, will allow convenience stores to continue to serve the important consumer category that relies on access to convenience size drug products.⁸

IV. Extension of Benefits of Guaranty to Party Delivering Drug Products for Further Repacking, Labeling

Mechanical Servants understands that FDA and drug manufacturers may be concerned about the regulatory implications associated with providing drug relabelers with drug product inner pouches that do not bear full drug labeling information. As a review of the inner pouch of the sample provided with this letter displays, many of these inner pouches currently contain all required drug labeling information, albeit in a type size that raises questions about readability. In fact, prior to the implementation of the Drug Facts Rule, many of these inner pouches could be introduced lawfully into interstate commerce in the absence of an outer wrapper. Thus, manufacturers assumed little or no risk of a misbranding violation under 21 U.S.C § 352 when these pouches were supplied to relabelers.

However, with the implementation of the Drug Facts Rule, it is almost impossible to label these inner pouches in a manner that would allow them to be sold in the absence of an outer wrapper, unless the pouches were significantly increased in size. Therefore, because these pouches cannot comply with the Drug Facts Rule, supplying these pouches to relabelers, now raises possible manufacturer liability for misbranding caused by the relabeler. See 21 U.S.C. §§ 331, 352. Mechanical Servants believes that an FDA regulation that extends the guaranty

⁸ While we have no direct information on the intention of drug manufacturers, there appears to be a concern within the industry that the labeling burden associated with the inner pouches will make it unprofitable to continue to supply convenience size drug product relabelers, such as Lil’ Drug Store and Mechanical Servants.

Kirkpatrick & Lockhart LLP

Dockets Management Branch

May 13, 2002

Page 8

exemption set forth in 21 U.S.C. § 333(c), can allay the manufacturer's concern about such liability.

Currently, the Act provides that a party will not be liable for receiving, or subsequently delivering a drug that violates certain provisions of section 301 of the Act (21 U.S.C. § 331) as long as the party has a guaranty signed by the person from whom the party received the drug shipment. In order to be effective, the guaranty must state that the drug shipment is not adulterated or misbranded within the meaning of the Act. Id. Mechanical Servant's will request that the statutory and regulatory benefits of such a guaranty be established and recognized for a manufacturer that delivers drug product to another party, such as a relabeler. In this case, the relabeler would provide a guaranty that, upon completion of processing, labeling, or repacking, the drug product will not violate section 301 of the Act. This type of guaranty, generally referred to as a "reverse guaranty", is recognized by many in the drug industry as a measure to assure private compliance with the Act. However, neither the Act nor FDA's implementing regulations affirmatively protect the holder of a "reverse guaranty" from the penalties associated with a violation of section 301 of the Act. Interestingly, FDA regulations exempt a manufacturer from complying with the drug labeling requirements when the manufacturer ships drug product to another party, such as a relabeler, for further processing, labeling, or repacking, as long as the manufacturer obtains an agreement from the relabeler that the drug will be fully compliant once the processing, labeling, or repacking is completed. However, the exemption becomes "void ab initio" once the drug product leaves the relabeler's facilities. See 21 C.F.R. § 201.150. Thus, even with such an agreement, the manufacturer can be held criminally liable for the relabeler's subsequent violations of the Act.

Mechanical Servants does not believe that the public is served better by not extending the protection of an FDA guaranty to the shipping manufacturer. Because drug manufacturers cannot assure that they will be exempt from criminal liability for a relabeler's violation of the Act, there is a concern that drug manufacturers will decide to discontinue serving the consumers of convenience size drug products. As explained in the Lil' Drug Store citizen petition, not only will an important consumer category be hurt by such a business decision, companies that have long met the needs of these consumers will be forced out of business.

Mechanical Servants believes that it represents a model of regulatory compliance within the drug industry and it would not shy away from assuming complete liability for responsibilities outlined in an FDA "reverse guaranty." It would expect that all members of the drug industry would agree that consumers will be better served, in terms of cost, convenience, and choice, if parties within the drug industry are provided with additional freedom to contract and shift appropriate regulatory burdens through contracts or guarantees. Extending the exemption from criminal liability to drug manufacturers who obtain an FDA "reverse guaranty" from companies that provide further processing, repacking, or labeling will certainly go a long way in assuring these benefits.

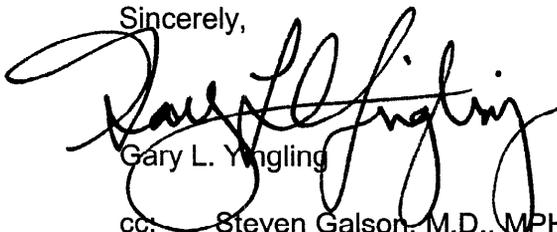
Kirkpatrick & Lockhart LLP

Dockets Management Branch
May 13, 2002
Page 9

V. Conclusion

Mechanical Servants is hopeful that these comments will assist FDA as it moves forward on a proposed rule to address convenience size OTC drug product labeling. Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary L. Yingling", written in a cursive style. The signature is positioned above the printed name.

Gary L. Yingling

cc. Steven Galson, M.D., MPH

Dr. Charles Ganley, Director, FDA Division of Over-the-Counter Drug Products
Robert Heller, FDA, CDER Office of Compliance