

October 9, 2002

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Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services, Room 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

**CITIZEN PETITION**

On behalf of our client, Mechanical Servants, Inc. ("Mechanical Servants"), the undersigned submits this petition under Sections 303(c), 503(a), and 701(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). The petitioner hereby requests the Commissioner of the Food and Drug Administration ("FDA") to set forth, through implementation of a guidance or policy statement, the "inner package" labeling requirements for most convenience size drug products where fully compliant labeling appears on the outer container of the retail package. The petitioner further requests the Commissioner to implement a regulation that acknowledges and accepts a "reverse guaranty" as a basis for exemption from certain liabilities under the FFDCA.

**A. Action Requested**

Petitioner asserts that the recently implemented regulation, *format and content requirements for over-the-counter (OTC) drug product labeling*, set forth at 21 C.F.R. § 201.66 (hereinafter "Drug Facts rule") could have the unintended effect of devastating the convenience size OTC drug market unless specific steps are taken in order to avoid such an outcome. In the interest of the public health, to assure the continued availability of OTC drugs in establishments that would otherwise not have such products available, and to continue to provide consumers with the convenience size OTC drug packages that are popular for storage in purses, briefcases, and travel gear for future use, the petitioner respectfully requests that the Commissioner take the following actions:

1. Implement a guidance or policy statement setting forth the "inner package" required labeling statements for most convenience size OTC drug products with fully compliant "outer package" labeling. Petitioner believes that the required label information under these circumstances should be limited to the drug product proprietary name, the lot number, and the expiration date.

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2. Implement an FDA regulation that extends the “guaranty” exemption set forth in FFDC § 303(c) (21 U.S.C. § 333(c)) to manufacturers that deliver drug product to another party, such as a relabeler, where the receiving party guarantees that, upon completion of processing, labeling, or repacking, the drug product will not violate section 301 of the FFDC (21 U.S.C. §331).

**B. Statement of Grounds**

**I. Factual Basis for Request**

On March 17, 1999, FDA finalized a regulation requiring all OTC drug manufacturers to adopt standardized labeling format and content requirements in connection with the outer retail package of OTC drugs (hereafter called the “Drug Facts rule”).<sup>1</sup> In implementing this regulation, FDA intended to significantly improve readability, help consumers locate and read important health and safety information, and promote quick and effective product comparisons so as to allow consumers to select the most appropriate product.<sup>2</sup>

Understanding that manufacturers that package OTC drug products in small containers could have some difficulty meeting the outer retail package labeling requirements, FDA provided certain Drug Facts rule modifications for small packages.<sup>3</sup> FDA also offered manufacturers, packers, and distributors the opportunity to submit a written request for exemption or deferral from certain requirements if those requirements are inapplicable, impractical, or contrary to the public health or safety.<sup>4</sup>

As a relabeler of convenience size OTC drug products (i.e., packages sold to the public that contain no more than one or two doses of OTC drug products), Mechanical Servants, recognizes the challenges associated with complying with the Drug Facts rule. However, because it recognized the benefits of the standardized system, Mechanical Servants quickly set about reviewing its labeling format to identify changes necessary to meet the regulatory requirements. Ultimately, it adopted a new multipart resealable outer retail package label that allowed full compliance with the Drug Facts rule without changing the OTC drug package size.

Then, in response to a citizen’s petition from Lil’ Drug Store Products, Inc. (“Lil’ Drug Store”) asking FDA to allow truncated retail package labeling for convenience size OTC drug products, FDA issued a notice delaying the Drug Facts rule compliance date with respect to convenience size OTC drug products, and notified the public that it intended to issue a proposal to modify the Drug Facts rule for such OTC drug packages.<sup>5</sup>

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<sup>1</sup> 64 Fed. Reg. 13,286 (March 17, 1999); 21 C.F.R. § 201.66.

<sup>2</sup> *Id.*

<sup>3</sup> 21 C.F.R. § 201.66(d)(10).

<sup>4</sup> 21 C.F.R. § 201.66(e).

<sup>5</sup> Lil’ Drug Store Products, Inc. Citizen Petition to FDA, April 27, 2001, Docket No. 01P-0207/CP1 (hereafter “Lil’ Drug Store Petition”); 66 Fed. Reg. 16,304 (April 5, 2002); Letter to

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For a number of reasons, Mechanical Servants disagrees with the need to modify the Drug Facts rule as it relates to convenience size OTC drug packages, and these reasons are clearly set forth in the comments submitted to FDA on May 13, 2002.<sup>6</sup> Mechanical Servants disagreed with Lil' Drug Store's position that consumers of convenience size OTC drug products require less drug product information at the point-of-purchase than those purchasing regular multiple-dose packages of OTC drugs. In fact, there is a heightened need for adequate and complete directions for use on the outer retail package because, as noted in the Lil' Drug Store petition<sup>7</sup>, 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.

While not supporting Lil' Drug Store's proposed modification to the Drug Facts rule, in its May 13, 2002 comments to FDA, Mechanical Servants stated that it would support an FDA policy limiting the information that must appear on the "inner package" of a convenience size OTC drug product. Because such drug products are generally intended for immediate use, there is little concern that the inner package will become separated from the outer retail packaging. With no safety benefit derived from duplicative labeling, Mechanical Servants believes that, where fully compliant labeling appears on the outer container of the retail package, the "inner package" labeling in most convenience size drug products can be limited to (1) an identification of the proprietary name of the drug product, (2) the lot number, and (3) the expiration date. Mechanical Servants also asserted the need for FDA to acknowledge and accept a "reverse guaranty" as a basis for exemption from certain liabilities under the FFDCa.

Because of the burdens placed on drug manufacturers in connection with the inner package labeling of "convenience size" drug products, Mechanical Servants believes that the above noted actions are required to assure the continued viability of the "convenience size" OTC drug industry. While Mechanical Servants has 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 products to relabelers, such as Lil' Drug Store and Mechanical Servants.<sup>8</sup> This important sector meets the needs of consumers who may be temporarily limited to shopping at a convenience store or non-drug store location (e.g., hotels, cruise ships, airports, campgrounds). There are over 120,000 convenience stores in the United States, with over one

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James M. Nikrant from Steven Galson, Acting Director, FDA Center for Drug Evaluation and Research, January 18, 2002, Docket No. 01P-0207/Let 1.

<sup>6</sup> Mechanical Servants, Inc. Comments to FDA, May 13, 2002. Docket No. 90P-0201.

<sup>7</sup> Lil' Drug Store petition at 4.

<sup>8</sup> *Id.* at 6, stating that "...as a result of the cost associated with implementing the new OTC labeling requirements in the Convenience Size OTC Product Industry, our partners (leading pharmaceutical companies) are considering discontinuing production of all or some of the single-dose pouches which are repacked, marketed and distributed by the Convenience Size OTC Products industry."

billion dollars in sales generated by these stores in the health and beauty category alone. These sale statistics establish broad consumer reliance on such venues as a source for safe and effective health-related products.

Recognizing that issues concerning the OTC drug product inner package label and the guaranty fall outside the scope of the proposed rulemaking concerning the Drug Facts rule, Mechanical Servants stated that it planned to submit a citizen's petition to request these actions. Through this submission, Mechanical Servants sets forth the regulatory basis for requesting these actions.

## **II. Legal Basis for Limiting Labeling Information that Appears on the Inner Pouch of Convenience Size OTC Drug Products**

The Drug Facts rule applies only to the outside package or outer wrapper of the retail package.<sup>9</sup> 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. 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.<sup>10</sup> However, in some circumstances, it is not practical or necessary to require drug label information to appear on the inner packaging. For example, drug label information is not required on the back lining of a blister pack card of drugs. This policy makes sense because any label information on the blister card would be defaced when individual dosage units are removed.

The problems associated with labeling blister pack cards also apply to most convenience size drug product inner packages. Inner packages, usually in pouch form<sup>11</sup>, generally are just large enough to hold a single dose of an OTC drug product, as does a single dosage unit from a blister card. Review of the enclosed "convenience size" OTC drug product presents a good example of the typical inner pouch size, which usually does not allow much more than eight

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<sup>9</sup> 21 C.F.R. § 201.66.

<sup>10</sup> The FFDCA defines the "label" as "a display of written, printed, or graphic matter upon the *immediate container* of any article. See FFDCA § 201(k) (21 U.S.C. § 321(k)) (emphasis added). At a minimum, the label must bear an active ingredients statement (section 502(e) of the FFDCA (21 U.S.C. § 352(e)), the name and address of the manufacturer, relabeler, or distributor (Section 502(b)(1) of the FFDCA (21 U.S.C. § 352(b)(1)), a net contents statement (section 502(b)(2) of the FFDCA (21 U.S.C. § 352(b)(2)), a lot number (21 C.F.R. § 201.18), and an expiration date (21 C.F.R. § 201.17). See also FDA's comments on small container drug products 59 Fed. Reg. 43,386, at 43,399 (August 23, 1994). 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)).

<sup>11</sup> 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, revised July 26, 1999.

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square inches of labeling space. The required "label" information would therefore 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.<sup>12</sup> 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.<sup>13</sup>

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 must appear 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 current symptoms.<sup>14</sup> Thus, duplicative labeling merely increases costs to the consumer without increasing safety.

The FFDCA 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

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<sup>12</sup> Mechanical Servants recognizes 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 consumers could actually read the required labeling information, which raises the issue of misbranding under FFDCA §502(c) (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.

<sup>13</sup> There are probably some that would suggest that the convenience size drug product inner pouch is the "immediate container." By "immediate container" Mechanical Servants is referring to the portion of the packaging that must bear the drug "label" information." See FFDCA § 201(k) (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 FFDCA §201(l) (21 U.S.C. § 321(l)). The back lining of a blister pack also appears to be excluded from the definition of "immediate container". Because of the impracticalities associated with meeting the full label requirements on most convenience size drug product inner containers, Mechanical Servants believes that the inner containers should also be excluded from the definition of "immediate container."

<sup>14</sup> Lil' Drug Store Petition, page 4.

container.”<sup>15</sup> 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 bear (1) the proprietary name of the drug, (2) the lot number, and (3) 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 labeling information on the inner pouch, this should be a voluntary decision. Limiting the required inner pouch labeling requirements associated with convenience size OTC drug products will minimize packaging costs and thereby address some of the economic concerns raised by the Lil’ Drug Store citizen petition.

Simplification of the labeling process will encourage drug manufacturers to continue to assist in packaging convenience size drug products, for 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 only required where it is most effectively placed (i.e., the convenience size drug product outer package), the manufacturer of the inner pouches will be relieved of the cost burden, thereby allowing convenience drug product relabelers to continue to serve the important consumer category that relies on access to convenience size drug products.

### **III. Legal Basis for Extending the 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 review of the inner pouch of the sample provided with this letter shows, many of these inner pouches 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 have been introduced lawfully into interstate commerce in the absence of an outer wrapper. Thus, manufacturers assumed little or no risk of a misbranding violation under FFDC A §502 (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 at retail in the absence of an outer wrapper, unless the pouches were significantly increased in size. Therefore, because complying with the Drug Facts rule would be difficult, supplying these pouches to relabelers now raises possible manufacturer liability for misbranding caused by the relabeler.<sup>16</sup> Mechanical Servants believes that an FDA regulation that extends the guaranty exemption set forth in FFDC A § 303(c) (21 U.S.C. § 333(c)), can allay the manufacturer’s concern about such liability.

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<sup>15</sup> See footnote 13.

<sup>16</sup> FFDC A §§ 301, 502 (21 U.S.C. §§ 331, 352).

Currently, the FFDCa provides that a party will not be liable for receiving, or subsequently delivering a drug that is adulterated or misbranded as long as the party has an "FDA guaranty" signed by the person from whom the party received the drug shipment.<sup>17</sup> In order to be effective, the FDA guaranty must state that the drug shipment is not adulterated or misbranded within the meaning of the FFDCa.<sup>18</sup> Mechanical Servants requests 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. The relabeler would then provide a guaranty that, upon completion of processing, labeling, or repacking, the drug product will not be adulterated or misbranded within the meaning of the FFDCa. This type of guaranty, generally referred to as an "FDA reverse guaranty", is recognized by many in the drug industry as a measure to assure private compliance with the FFDCa. However, neither the FFDCa nor FDA's implementing regulations affirmatively protect the holder of an "FDA reverse guaranty" from the penalties associated with a violation of the adulteration/misbranding provisions of the FFDCa.

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.<sup>19</sup> Thus, even with such an agreement, the manufacturer can be held criminally liable for the relabeler's subsequent violations of the FFDCa.

Mechanical Servants does not believe that the public is served better by not extending the protections 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 FFDCa, there is a concern that drug manufacturers will decide to discontinue serving the consumers of convenience size drug products. 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.

Clearly, the FFDCa provides the Commissioner with the authority to implement such a regulation. Section 502(a) of the FFDCa (21 U.S.C. § 353(a)) directs the Commissioner to promulgate regulations exempting from any labeling or packaging requirements of the FFDCa drugs which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed ("secondary establishments"). This exemption is conditioned upon a requirement that such drugs are not adulterated or misbranded when removed from the secondary establishment. Pursuant to this authority, FDA could issue a regulation that provides an exemption from the FFDCa misbranding and adulteration provisions to manufacturers who

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<sup>17</sup> FFDCa § 303(c) (21 U.S.C. § 333(c)).

<sup>18</sup> *Id.*

<sup>19</sup> 21 C.F.R. § 201.150.

obtain an "FDA reverse guaranty," as specified above, from the secondary establishment. The FDA can then hold the secondary establishment responsible for meeting the condition that the drugs can neither be adulterated or misbranded under the FFDCa when they leave the establishment. To assure good faith on the part of the original manufacturer in connection with an "FDA reverse guaranty," FDA can condition the exemption of the original manufacturer from certain FFDCa liabilities to a requirement that the original manufacturer must fully cooperate with any investigation concerning the secondary establishment's alleged misbranding or adulteration of drug product purchased from the original manufacturer.

Mechanical Servants believes that it represents a model of regulatory compliance within the drug industry and it would willingly assume 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.

**C. Environmental Impact**

As provided in 21 C.F.R. § 25.31, neither an environmental assessment nor an environmental impact statement is required.

**D. Economic Impact**

As provided in 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

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**E. Certification**

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

Sincerely,

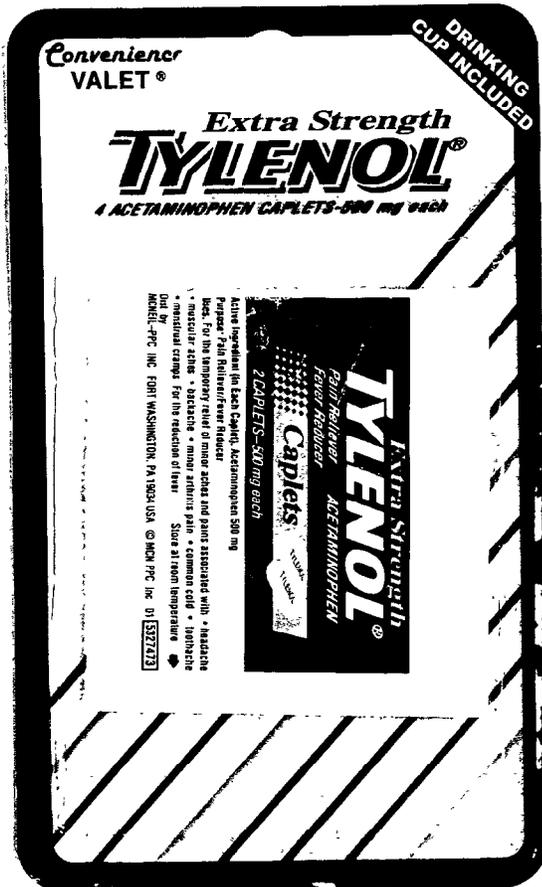
A handwritten signature in black ink, appearing to read "Gary L. Yingling". The signature is written in a cursive style with a long horizontal stroke extending to the right.

Gary L. Yingling  
Counsel for Mechanical Servants

Enclosure

cc: Steven Galson, MD, MPH, Deputy Director, Office of the Center Director, CDER  
Charles Ganley, MD, Director, Division of OTC Drug Products, CDER  
Robert Heller, Consumer Safety Officer, OTC Compliance Team, CDER

Photocopy of Sample "Convenience Size" OTC Drug Product Labels



Front of retail package

EXP 2/06  
FCM115



Distributed by  
Convenience VALET® Division  
Mechanical Servants, Inc. Melrose Park, Illinois 60160

Drug Facts	
<b>Active Ingredient (in each caplet)</b> Acetaminophen 500 mg	<b>Purposes</b> Pain reliever/fever reducer
<b>Uses</b> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> <li>• headache</li> <li>• muscular aches</li> <li>• backache</li> <li>• arthritis</li> <li>• the common cold</li> <li>• toothache</li> <li>• menstrual cramps</li> </ul> • reduces fever	
<b>Warnings</b> Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.	

↓ Lift Here ↓

Back of retail package (S&S-1887)



Active Ingredient (in Each Caplet): Acetaminophen 500 mg  
 Purpose: Pain Reliever/Fever Reducer  
 Uses: For the temporary relief of minor aches and pains associated with • headache • muscular aches • backache • minor arthritis pain • common cold • toothache • menstrual cramps For the reduction of fever Store at room temperature  
 Dtd by: MCKEIL-PPC INC FORT WASHINGTON, PA 19034 USA © MCK-PPC Inc 01 5327473

Front of inner pouch

**Warnings: Alcohol Warning:** • If you consume 3 or more alcoholic drinks every day ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.  
**Do Not Use:** • with any other product containing acetaminophen • for more than 10 days for pain unless directed by a doctor • for more than 3 days for fever unless directed by a doctor  
**Stop Using and Ask a Doctor if:** • symptoms do not improve • new symptoms occur • pain or fever persists or gets worse • redness or swelling is present  
**Do not exceed recommended dose.** Keep this and all drugs out of the reach of children. In case of accidental overdose, contact a physician or poison control center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.  
**Directions:** Adults and children 12 years of age and older: Take 2 Caplets every 4 to 6 hours as needed. Do not take more than 8 caplets in 24 hours, or as directed by a doctor. Children under 12 years: Do not use this adult Extra Strength product in children under 12 years of age. This will provide more than the recommended dose (overdose) of TYLENOL® and could cause serious health problems. Do not use if pouch is opened. Inactive ingredients: Carnauba Wax, Castor Oil, Cellulose, Corn Starch, FD&C Red #40, Hydroxypropyl Methylcellulose, Magnesium Stearate, Sodium Starch Glycolate, Titanium Dioxide.

Back of inner pouch