

Label Readability Analysis of FDA Regulated OTC Drug Products and Cosmetics

by

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### **Abstract**

Information on a product's label indirectly affects the wellbeing of society. Even though physicians help with treatment options, the readability of the information on drug labels may be essential for acquiring complete guidance. Hence, literacy plays an important role in the treatment options that health care professionals can suggest to consumers. Patients with low literacy cannot read and understand complicated terms on product labels. The aim of this review was to determine the readability of FDA regulated OTC product labels and cosmetic labels to check whether they are likely comprehensible to the general public. To determine readability, the average grade level and reading ease of 20 OTC products (10 approved by monograph & 10 approved by the NDA route) and 20 cosmetic labels were measured. The mean average grade level of both OTC products and cosmetics was 7<sup>th</sup> grade. In terms of reading ease, reading ease of OTC products was 63.6 and reading ease of cosmetics was 59.4. Therefore, both OTC and cosmetic labels should be improved because the recommended grade level is 4<sup>th</sup> to 5<sup>th</sup> grade for medication labels to be easily read and understood, especially by low literacy consumers.

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## **Introduction**

The responsibility towards one's own health and medical care has recently shifted more to consumers rather than health care providers (Vigilante & Wogalter, 1999). A large number of Americans use over-the-counter (OTC) products for their daily health needs (FDA, 2018a). OTC drugs are defined as medications that are safe and effective for use by consumers without seeking guidance from a health care professional. CDER's Office of Drug Evaluation IV handles FDA's review of OTC drugs (FDA, 2015a). OTC products are marketed under monographs or new drug applications (NDA). OTC drug monograph is defined as a type of "recipe book" that includes all the admissible ingredients, doses, labeling and formulations. Monograph may also include other important information, such as drug interactions. Monographs are listed in Section 300 of the Code of Federal Regulations. If the product conforms to a final monograph, then it may be marketed without additional FDA approval (FDA, 2015a). On the other hand, an NDA is defined as the new drug that has enough evidence on the product's safety and effectiveness in its present state, proposed labeling, and formulation prior to marketing (FDA, 2019). If a product does not conform to a final monograph, then it requires further FDA review, and requires submission of an NDA and approval by the FDA prior to marketing (FDA, 2015a).

OTC drugs are available in many forms. Some of them are liquids, ointments, tablets, syrups, or eye drops. To buy OTC products, a doctor's prescription is not necessary. Still, OTC products are real drugs possessing side effects and drug interactions. Serious events can occur if they are not used properly (Poison Control, 2019). It is crucial to note that OTC agents are comparatively safe to use only if the label is thoroughly read, but can be dangerous if the risks are unknown (Trivedi, Trivedi, & Hannan, 2014). Label is defined as the "display of written, printed, or graphic matter upon the immediate container of any article" (FDA, 2018b).

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Subsequently, consumers must be able to readily collect information from non prescription medication labels (National Consumers League, 2007). The label is the only protection from the incorrect use of medications as OTC products are taken without the supervision of a medical practitioner (Trivedi et al., 2014). Accordingly, reading the drug product information on the label is crucial.

Poorly outlined directions had a great impact on nearly half of the geriatric population as they did not take their medications regularly (Morrow, Leirer, & Sheikh, 1988). Before 1999, uses, warnings and directions were hardly presented on the label, but, after the introduction of the “Drug Facts Label” in March 1999, the information has become reliable for consumers (FDA, 2015b). At that period in the Drug Facts Label, words such as “indications” were replaced by “uses” and words like “contra-indications” and “precautions” were replaced by other simpler words that were easy to read and understand (FDA, 2015b). FDA published OTC Drug Facts Label regulation in the Federal Register in March 1999. The OTC labeling rule regulates nearly 100,000 OTC products (FDA, 2015b). New ‘Drug Facts’ labeling regulation is listed in 21 CFR 201.66 which includes all OTC drug products whether marketed under an approved NDA or OTC drug monograph. In the case of extended tubes, such as tooth pastes and topical ointments, using columns as part of the standard labeling format may remarkably improve readability (FDA, 2018c).

Every OTC label contains a ‘Drug Facts’ Section that should be read thoroughly before taking or giving the medicine to avoid serious issues. In this section, the information is placed in the following order:

- Active ingredient- Important ingredient that helps the medicine to work

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- Purpose, such as antihistamine
- Uses- To treat the symptoms
- Warnings- To use or not use along with other medicines
- Directions- How to use and dosage instructions
- Other information- Storage instructions
- Inactive ingredients- Not meant to treat the symptoms (Poison Control, 2019)

This section helps consumers choose and use the medicines effectively based on symptoms. Important information is enclosed in this section, such as avoiding taking two medicines with the same active ingredients at the same time. Therefore, it is important to read the drug facts label (Johnson & Johnson Consumer Inc., 2016). Sample Drug Facts label of OTC monograph and sample Drug Facts label of OTC NDA were included in Appendices D and E.

As medical information can be difficult for consumers to understand, label comprehension studies should be conducted to measure consumers' medical literacy. Then, the 'Drug Facts Label' should be designed based on the layout, organization, and the simplification of complex information (Ryan & Costello-White, 2017). It is assumed that regulations that enable consumers to read and understand drug facts will help them to use the product safely and effectively (Federal Register, 1999).

The label is an important section that gains attention by the consumers and health professionals when purchasing nonprescription products (Holt et al., 1992; Shrank, Avorn, Rolon, & Shekelle, 2007). Proper and accurate labeling also plays an important role in the



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prevention of serious adverse events (Sundar, Becker, Bello, & Bix, 2012). Not only is the physical presentation of the label important, but also the language on the label must be simple and easy to understand for the safe use of medications (King et al., 2011).

Factors, such as headings, space, increased font size, and use of simple language, may improve the readability and comprehension of non-prescription labels (Shrank et al., 2007). Height of the letters and parallel compression are also important considerations in defining readability (Watanabe, 1994). Additionally, consumers preferred the information with titles and space on the labels to avoid difficulty while reading (Wogalter & Vigilante, 2003; Therapeutic Goods Administration, 2013).

The elderly population is the biggest consumers of OTC drug products in the United States (Pawaskar & Sansgiry, 2006). They are highly susceptible to the misuse of OTC products due to several disease conditions and concurrent use of OTC with prescription products. The information on non-prescription drug labels should be written in a font level of at-least 6 points (Federal Register, 1999). Older adults especially need label information to be in big font that is easy to read. It is easy to read when the instructions on the label are provided in the font level 10-14 points (Pawaskar & Sansgiry, 2006). Therefore, the label format with larger print might be helpful for conferring OTC drug information, especially to this population (Pawaskar & Sansgiry, 2006).

The elderly population in the health care community, a group particularly vulnerable to side effects of the drug, constitutes largest in terms of percentage of population, are facing challenges to read the smaller font and understand the complex terms on the nonprescription labels. There is no specific grade level criteria mentioned in the regulations, but, the average US

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reading ability is considered to be 8<sup>th</sup> grade level (Trivedi et al., 2014). The National Adult Literacy Survey reported that about 25% of the adult population in the United States could not read and understand labels, which are above 5<sup>th</sup> grade level. In August 2010, FDA published a guidance document regarding label readability which contains “Nonbinding Suggestions” admits that the standard practice to present the medical information is 4<sup>th</sup> to 5<sup>th</sup> grade level. It recommends that attempts should be made to present the information on nonprescription labels at 4<sup>th</sup>-5<sup>th</sup> grade level, and no higher than 8<sup>th</sup> grade level (Trivedi et al., 2014).

OTC labels for acetaminophen still fail to communicate the risk of liver damage (Rojas & Li, 2017). The drug facts label must adequately disclose the important information essential for the safe and effective use of the medicines (Catlin & Brass, 2018). The fundamentals such as, font size, spacing between lines and color contrast that are extracted from the research of OTC labels are also applicable to other types of consumer product labels (Ryan & Costello-White, 2017).

Cosmetics are defined as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance” by the Federal Food, Drug and Cosmetic Act, 1938. Examples of cosmetics are deodorants, perfumes, shampoos, nail products, lipsticks, and hair color, in addition to any substance intended for use as a component of a cosmetic product (FDA, 2017). Cosmetics are regulated by the FDA through the:

- Federal Food, Drug and Cosmetic Act (FD&C Act) of 1938, as revised
- Fair Packaging and Labeling Act

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However, cosmetics do not require FDA pre-approval, obligatory establishment registration, and reporting regarding the ingredients. It is the manufacturer's responsibility to assure that the ingredients in cosmetic products are safe and are labeled accurately in accordance with the law (Liberty Management Group Ltd, n.d.).

The 'Safe Cosmetics Act' of 2010 gave the power to FDA to minimize the chemicals in cosmetics and to limit the risk of carcinogens and endocrine disruptors. The FD&C Act banned the marketing of adulterated and misbranded cosmetic products in interstate exchange (Ecomundo, 2014). The Food and Drugs Administration is also competent for coloring agents. The FDA has setup limited standards for manufacturers to determine the safety of their own products:

- Risk description
- Hazard determination
- Risk classification

The FD&C Act developed a program for manufacturers named the "Voluntary Cosmetic Registration Program," which includes company registration and statement regarding cosmetic product ingredients. Label statements required by the FD&C Act must appear both outside and inside the package (Ecomundo, 2014).

In one study, subjects complained about the readability of cosmetic labels as the type size and color contrast on the label posed difficulties for them to read. Consequently, readability should be improved to avoid allergic reactions due to coloring agents (Yazar, Seimyr, Novak, White, & Liden, 2014). A sample of a cosmetic label is included in Appendix F.

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To evaluate the readability of OTC product labels and cosmetic labels, two aspects need to be assessed. “Readability” is defined as the capability of the individual to read and understand the written material. It is measured in terms of grade level (ranges on a scale from 1-12) and reading ease (determined through the Flesch-Kincaid reading ease scale of 1-100). These two aspects will provide an overall understanding of the readability of the given text. There are various tests available to determine the readability of any given text (Badarudeen & Sabharwal, 2010).

According to Badarudeen and Sabharwal (2010), most widely used readability tools in the healthcare industry are, Flesch Reading Ease scale to determine the reading ease; Flesch-Kincaid Grade Level, SMOG Index, Gunning Fog Index are all different tests used to determine the grade level of the text. All of these tests including Cloeman-Liau Index and Automated Readability Index use different mathematical formulae to calculate the grade scores. The average of these test scores would give an accurate grade level. All these tests are available on various paid website services at low cost (Badarudeen & Sabharwal, 2010). Based on the studies that assessed the readability of other similar patient education materials, Flesch-Kincaid reading ease scale and Average grade level were used to determine the readability of OTC products and cosmetics.

In the previously mentioned study, Badarudeen and Sabharwal (2010) used the Flesch Reading Ease since it is one of the most widely used measurement tools for calculating readability. It gives the reading ease score between 0 and 100. A higher score means the text is easier to read; where as a lower score means the text is difficult to read. This scale is also used by various institutions in determining readability of written materials. For instance, State of

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Florida requires the Flesch Reading Ease score to be no less than 45 for all insurance policies (Trivedi et al., 2014).

The purpose of this research was to evaluate the average grade level and reading ease of OTC (marketed either via monograph or NDA) and cosmetic labels to determine if either meets the readability requirements. The review sought to address the question: How does the readability of FDA-regulated OTC product labels vary compared to cosmetic labels? The answer to this question helps us to know if the groups differ and either meets the readability requirements.

### Methods

To compare and analyze the grade level and reading ease of OTC drug products regulated under NDA and monographs, and cosmetics. Samples of 20 OTC drug product labels (10 monographs & 10 NDA) and 20 cosmetic labels, each from a different category were selected at random. The text from these labels was analyzed using a paid-service tool, [www.readable.com](http://www.readable.com) (“Readable.com,” 2019). The text was entered into a textbox provided in the website, which then used mathematical formulas to determine the readability scores. This website was selected as it was user-friendly and has many helpful features. This website used Flesch-Kincaid Reading Ease readability test which helps to determine the ease by which a piece of text could be understood. The Flesch reading ease analyzes the ease of reading on a scale from 0 to 100. The higher the reading score, the easier the text can be read. This website also used the following grade level tests to analyze the grade level of the text: Flesch-Kincaid Grade Level, Gunning Fog Score, Cloeman-Liau Index, SMOG Index, and Automated Readability Index to calculate the average grade level. Average grade level was used rather than individual test grade level to get a more accurate result (“Readable.com”, 2019).

The Flesch-Kincaid Reading Ease values and the grade level of the text: Flesch-Kincaid Grade Level, Gunning Fog Score, Cloeman-Liau Index, SMOG Index, Automated Readability Index and Average Grade Level values of OTC products (monographs & NDA), and cosmetics were collected for all 40 samples (Appendices A, B, and C).

After obtaining reading ease and average grade level values, statistical analyses were performed to determine the mean reading ease scores and the mean average grade level of OTC drug products (monographs & NDA) and cosmetics. Two two-tailed unpaired t-Tests were

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conducted to examine any of the differences between the mean reading ease scores of the OTC product labeling to that of the cosmetic labeling. A second set of two-tailed unpaired t-Tests were done to determine any of the differences between the mean average grade level of the OTC product labeling to that of the cosmetic labeling.

### Results

To evaluate the readability of OTC drugs (monographs & NDA) and cosmetics, two variables were analyzed: average grade level and reading ease. In terms of the average grade level (calculated by averaging the results of Flesch-Kincaid Grade Level, Gunning Fog Score, Cloeman-Liau Index, SMOG Index, and Automated Readability Index tests), OTC products (monographs & NDA) had a mean average grade level of 7.24 and cosmetics had a mean average grade level of 7.66, shown in Table 1. The average grade level of both OTC products and cosmetics fell in 7<sup>th</sup> grade.

In terms of the reading ease (calculated through the Flesch-Kincaid Reading Ease test), the 20 OTC products (monographs & NDA) had a mean reading ease score of 63.66, and the 20 cosmetics had a mean reading ease score of 59.46 (see Table 1). Based on the results, OTC product labels (monographs & NDA) had a little better reading ease than manufacturer's cosmetic labels.

To further analyze the differences in the means of the two variables: average grade level and reading ease, two two-tailed unpaired t-Test statistical tests were done between the means of the OTC products and cosmetics (one for average grade level and one for reading ease). The results of the tests (p values) are shown in Table 1. Since the p values of the tests are higher than 0.05 alpha level ( $p > 0.05$ ), the differences between the means of the grade level and reading ease are determined to be statistically non-significant. This states that there is no statistically significant difference between readability of OTC products (monographs & NDA) in comparison to that of cosmetics.



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Table 1

Descriptive Statistics of Variables Average Grade Level and Reading Ease of OTC Products (Monographs & NDA) and Cosmetics

Variable	Category	N	Mean $\pm$ SD	95% Confidence Interval for Mean		'p'-Value
				Lower	Upper	
Average Grade Level	OTC (Monographs & NDA)	20	7.24 $\pm$ 0.82	6.85	7.62	0.2843
	Cosmetics	20	7.66 $\pm$ 1.54	6.94	8.38	
Flesch Reading Ease	OTC (Monographs & NDA)	20	63.66 $\pm$ 4.71	61.45	65.86	0.1469
	Cosmetics	20	59.46 $\pm$ 11.76	53.96	64.96	

### Discussion

The reading ease and the average grade level of 20 nonprescription medications (10 OTC monographs & 10 NDA), each from a different category and 20 cosmetics were evaluated. Most of the OTC drugs grade level fell between 6<sup>th</sup> and 8<sup>th</sup> grade. Although the average reading ability of the US population is 8<sup>th</sup> grade level, 5<sup>th</sup> grade level is suggested for medication labels (Trivedi et al., 2014). The mean average grade level of OTC products (monographs & NDA) was 7.6, and the mean average grade level of cosmetics was 7.24. Some of the cosmetics even surpassed the 8<sup>th</sup> grade level, such as silky personal lubricant, post shaving balm, mascara, infallible paints eye liner, and hair color remover. The readability within 4<sup>th</sup> to 6<sup>th</sup> grade level is termed “very easy” to “easy” to be read and understood by consumers (Kasesnik & Kline, 2011). The mean reading ease of OTC products was 63.6, which is considered “standard,” and the mean reading ease of cosmetics was 59.4, which is considered “fairly difficult”. The reading ease of some cosmetics, such as hair color remover, mascara, silky personal lubricant, post shaving balm, and eye liner, fell below the range 50. The reading ease of post shaving balm, silky personal lubricant, and mascara are 39.1, 38.5, & 44.8 respectively (Appendix C), which were well below the Flesch Reading Ease score of 45 mandated by the state of Florida, that is not acceptable (Trivedi et al., 2014). It is pertinent to consider health material in relation to the comprehensibility of people in the United States. Low literacy means less ability to understand the directions and risks presented on the label, potentially resulting in more medication or usage errors.

The FDA released a guidance document in August 2010 regarding the label readability studies of non-prescription products, which contains “unbinding suggestions” and identifies a basic system to present medical information at a 4<sup>th</sup> to 5<sup>th</sup> grade level (Trivedi et al., 2014). It

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suggests that efforts should be made to present the information on non-prescription labels between 4<sup>th</sup> and 5<sup>th</sup> grade reading levels and not higher than an 8<sup>th</sup> grade level (Trivedi et al., 2014).

It is important to convey relevant information to consumers' specific needs, considering factors, such as using products with other medications, low-literacy, language that uses medical words, age, and previous beliefs (Kasesnik & Kline, 2011). There are certain challenges to the Drug Facts Label (DFL) that help consumers in self selecting and using OTC medications (see Table 2).

Table 2

Challenges to Drug Facts Label (DFL) Reliability and Survivability Strategies

Source: Catlin & Brass, 2018

<b>Challenge to Label-Reliability</b>	<b>Explanation</b>	<b>Survivability Strategies</b>
Challenge 1: Stagnant and unchanged	Unable to meet the requirements of certain consumers, for instance: <ul style="list-style-type: none"> <li>• Low literacy</li> <li>• Visually impaired</li> <li>• Barriers to language</li> <li>• Elderly populations</li> <li>• Previous assumptions/confessions that overturn the DFL</li> </ul>	<b>Alternative label strategies</b> <ul style="list-style-type: none"> <li>• Icons, alerts to crucial drug related information</li> <li>• Using large font to make important drug-specific information more accessible</li> </ul> <b>Pharmacist</b> <ul style="list-style-type: none"> <li>• Reliable and trustworthy resource at the point of purchase</li> <li>• Helps customers to understand their requirements/restricti</li> </ul>

Challenge to Label-Reliability	Explanation	Survivability Strategies
		<p>ons</p> <ul style="list-style-type: none"> <li>• Presents the information and suggestions most pertinent to specific individual</li> <li>• Trains consumers about benefits/risks related to non prescription medications</li> </ul> <p><b>Technology</b></p> <ul style="list-style-type: none"> <li>• Effective and tailored methods with adjustable implementation</li> <li>• Question individual aspects and convey complete details</li> <li>• Multimedia use in order to create more attractive and conclusive content</li> <li>• Unrestricted delivery of material (messages, audio, and /or visuals)</li> </ul>
<p>Challenge 2: Informing complicated, multi-characteristic standards that help in decision making</p>	<p>Consumers struggle to comprehend more complicated label information</p> <p>Buyers continue to struggle to incorporate several labels required for the right choice and self -use of the product</p>	<p><b>Alternative label strategies</b></p> <ul style="list-style-type: none"> <li>• Figures to improve the warnings and to assist with the self selection of medications</li> <li>• Put together with educational attempts to help consumers understand DFL</li> </ul> <p><b>Pharmacist</b></p>

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Challenge to Label-Reliability	Explanation	Survivability Strategies
		<ul style="list-style-type: none"> <li>• Provides guidance to consumers regarding self selection</li> <li>• Communicates with consumers</li> <li>• Provides supplementary information about how to use</li> </ul> <p><b>Technology</b></p> <ul style="list-style-type: none"> <li>• Build interactive decision-making</li> <li>• Follow-up after the purchase: collection of information on use</li> </ul>

Results suggest that attempts should be made to increase the reading ease and to decrease the grade level to 4th and 5th grade for both cosmetics and OTC products (monographs & NDA), which will be easy to read and understand for the total United States population, especially older adults who constitute a majority of the US population. It is shocking to know that cosmetics have a higher-grade level and lower reading ease as they does not require a government approval. If cosmetic labels are not understood properly, then severe allergic reactions due to color additives could result. Therefore, efforts are required for over-the-counter (OTC) and cosmetic labels to be more standardized in terms of reading ease, grade level, and organization, which would make labels more effective to be read and understood, preventing potential medication and usage errors.

### **Conclusion**

The collected data of 20 OTC medication labels (10 monographs & 10 NDA) and 20 cosmetic labels does not show any statistically significant difference between FDA regulated OTC products and cosmetics. But the collected data shows the necessity of improving both FDA-regulated OTC (monographs & NDA) and manufacturers' cosmetic labels in terms of readability to avoid medication errors and allergic reactions, especially by older adults. More importantly, FDA and manufacturers need to be more sensitive to the results and change accordingly.

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**Appendix A: OTC drugs approved by the monograph route**

<b>OTC AGENT (Monograph)</b>	<b>Flesch Reading Ease</b>	<b>Flesch-Kincaid Grade Level</b>	<b>Gunning Fog Index</b>	<b>Coleman-Liau Index</b>	<b>SMOG Index</b>	<b>Automated Readability Index</b>	<b>Average Grade Level</b>
<b>Dove Men+Care (Antiperspirant)</b>	60.0	6.6	8.1	7.8	8.8	4.3	7.1
<b>Neutrogena (Sunscreen)</b>	66.2	6.4	7.2	9.5	8.8	6.1	7.6
<b>CVS Health (Antacid)</b>	58.6	6.7	7.6	9.1	8.7	5.4	7.5
<b>Walgreens (Eye Lubricant)</b>	67.3	5.5	7.2	6.8	8.5	3.5	6.3
<b>CVS Health (Nighttime Sleep-Aid)</b>	59.4	6.6	8.0	8.5	8.8	4.9	7.3
<b>CVS Health Chest Congestion Relief (Expectorant)</b>	60.5	6.8	8.7	9.3	9.3	5.7	7.9
<b>CVS Health Ear Drops (Ear Drying Aid)</b>	68.5	5.1	6.7	6.5	8.0	3.6	5.9
<b>Aquaphor (Skin Protectant)</b>	71.9	4.8	4.4	7.7	7.5	4.3	5.7
<b>CVS Health (Wart Remover Strips)</b>	68.6	5.1	7.6	6.5	8.3	3.5	6.2
<b>CVS Health (Anti-fungal) Cream</b>	64.7	7.3	8.5	9.9	9.9	7.8	8.6

## Appendix B: OTC drugs approved by the NDA route

<b>OTC AGENT (NDA)</b>	<b>Flesch Reading Ease</b>	<b>Flesch-kincaid Grade Level</b>	<b>Gunning Fog Index</b>	<b>Coleman-liau Index</b>	<b>SMOG index</b>	<b>Automated Readability Index</b>	<b>Average Grade Level</b>
<b>Children's Zyrtec (Anti-histamine)</b>	60.9	6.5	7.2	8.1	8.7	4.6	7.0
<b>Abreva Cream (Cold Sore Treatment)</b>	59.3	6.7	7.1	8.3	8.8	4.8	7.1
<b>Imodium A-D (Anti-diarrheal)</b>	69.1	5.6	6.9	8.5	9.0	5.2	7.0
<b>Well at Walgreens Nicotine Oral Gum (Stop Smoking Aid)</b>	66.9	6.3	8.4	8.9	9.5	5.6	7.7
<b>Aleve (Internal Analgesic)</b>	65.5	5.8	7.3	8.5	8.5	4.9	7.0
<b>AZO (Urinary Tract Analgesic)</b>	57.0	7.6	7.8	10.4	9.3	6.7	8.3
<b>Zantac 75 (Acid Reducer-H2-Antagonist)</b>	64.9	5.9	7.2	8.9	8.7	5.3	7.2
<b>Colgate Total (Anti cavity/Anti gingivitis)</b>	53.9	7.9	8.6	10.5	10.0	6.7	8.7
<b>Miralax (Hyperosmotic Laxative)</b>	66.2	5.9	7.4	7.1	8.8	3.8	6.6
<b>Oxytrol (Overactive Bladder Treatment)</b>	63.8	6.3	8.7	8.2	9.8	4.7	7.5

## Appendix C: Cosmetics

<b>Cosmetics</b>	<b>Flesch Reading Ease</b>	<b>Flesch-Kincaid Grade Level</b>	<b>Gunning Fog Index</b>	<b>Coleman-Liau Index</b>	<b>SMOG Index</b>	<b>Automated Readability Index</b>	<b>Average Grade Level</b>
<b>Revlon Eye Brow Pencil</b>	81.3	4.1	3.5	6.3	7.8	3.3	5.0
<b>Garnier Nutrisse Hair Color</b>	58.3	7.5	3.8	10.7	10.5	7.1	7.9
<b>Beauty 360 Cuticle Softener</b>	59.8	7.0	9.6	9.5	10.0	5.9	8.4
<b>Revlon Kiss Exfoliating Balm</b>	62.6	6.2	2.7	9.7	8.3	5.9	6.5
<b>Nad's Facial Wax Strips</b>	68.5	6.7	8.8	8.7	9.8	6.2	8.0
<b>LOreal Paris Hair Color Remover</b>	49.3	8.9	7.5	10.5	12.2	7.1	9.2
<b>LOreal Infallible Paints Eye Liner</b>	47.4	8.7	3.2	10.8	10.5	6.8	8.0
<b>Almay Instant Glow</b>	64.8	5.9	7.9	11.0	9.2	6.9	8.1
<b>Maybelline New York Lip Balm</b>	73.8	5.1	3.4	5.6	7.2	2.8	4.8
<b>Cover Girl Lip Color</b>	76.9	4.7	6.1	7.2	8.0	4.1	6.0
<b>Everpro Magnetic Powder</b>	58.6	7.3	9.2	10.6	10.0	6.9	8.8
<b>Revlon Mascara</b>	44.8	8.4	2.3	8.9	9.7	5.4	6.9
<b>Neutrogena Moisturizer</b>	70.4	5.0	3.1	7.4	7.5	4.1	5.4
<b>Beauty 360 Nail Polish Remover Pads</b>	62.0	6.6	7.6	8.9	9.3	5.3	7.5
<b>Neutrogena Shampoo</b>	56.4	7.2	8.9	11.3	9.6	7.2	8.8
<b>Fanci-Full Hair Color Stain Remover</b>	55.2	7.4	7.5	10.2	9.3	6.3	8.1
<b>Receutics Tone Corrector</b>	56.1	7.5	8.2	11.1	9.7	7.2	8.7
<b>Dove Post Shaving Balm</b>	39.1	8.9	8.8	12.0	9.3	8.4	9.4
<b>Kroger Silky Personal Lubricant</b>	38.5	10.1	10.4	12.6	11.4	8.4	10.5
<b>Revlon Nail Enamel</b>	65.5	5.3	6.9	7.8	8.5	4.8	6.6

**Appendix D: Monograph Drug Facts Label**

<b>Drug Facts</b>	
<b>Active ingredient</b> Aluminum Zirconium Tetrachlorohydrex GLY (20.0%).....	<b>Purpose</b> anti-perspirant
<b>Uses</b> ■ reduces underarm wetness   ■ extra effective	
<b>Warnings</b> For external use only	
Do not use on broken skin	
Ask a doctor before use if you have kidney disease	
Stop use if rash or irritation occurs	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ apply to underarms only   ■ before bed, apply three clicks of product to each underarm	
<b>Other information</b> Do not store over 115° F	
<b>Inactive ingredients</b> Cyclopentasiloxane, Dimethicone, Paraffin, Microcrystalline Wax, Fragrance (Parfum), Silica, Helianthus Annuus (Sunflower) Seed Oil, Dimethicone Crosspolymer, BHT.	



**Appendix E: NDA Drug Facts Label**

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each dose)</b> <span style="float: right;"><b>Purpose</b></span>                  Polyethylene Glycol 3350, 17 g..... Osmotic Laxative</p>	<p><b>Drug Facts (continued)</b></p> <p>If pregnant or breast-feeding, ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p>
<p><b>Use</b></p> <ul style="list-style-type: none"> <li>■ relieves occasional constipation (irregularity)</li> <li>■ generally produces a bowel movement in 1 to 3 days</li> </ul>	<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ <b>do not take more than directed unless advised by your doctor</b></li> <li>■ adults and children 17 years of age and older:                         <ul style="list-style-type: none"> <li>■ stir and dissolve one packet of powder (17 g) in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink</li> <li>■ use once a day</li> <li>■ use no more than 7 days</li> </ul> </li> <li>■ children 16 years of age or under: ask a doctor</li> </ul>
<p><b>Warnings</b></p> <p><b>Allergy alert:</b> Do not use if you are allergic to polyethylene glycol</p> <p><b>Do not use</b> if you have kidney disease, except under the advice and supervision of a doctor</p>	<p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at 20° - 25°C (68° - 77°F)</li> <li>■ tamper-evident: do not use if foil is open or broken</li> </ul>
<p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ nausea, vomiting or abdominal pain</li> <li>■ a sudden change in bowel habits that lasts over 2 weeks</li> <li>■ irritable bowel syndrome</li> </ul>	<p><b>Inactive ingredients</b> none</p>
<p><b>Ask a doctor or pharmacist before use if you are</b> taking a prescription drug</p>	<p><b>Questions or comments?</b>                  1-800-MiraLAX (1-800-647-2529)</p>
<p><b>When using this product</b> you may have loose, watery, more frequent stools</p>	<p>Bayer, the Bayer Cross, and MiraLAX are registered trademarks of Bayer © 2016 Bayer.                  Dist by: Bayer HealthCare LLC, Whippany, NJ 07981</p>
<p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ you have rectal bleeding or your nausea, bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition.</li> <li>■ you get diarrhea</li> <li>■ you need to use a laxative for longer than 1 week</li> </ul>	<p style="text-align: right;">Scanned with CamScanner</p>

## Appendix F: Cosmetic Label

**IMPORTANT:** HAIRCOLOR CAN CAUSE AN ALLERGIC REACTION WHICH, IN CERTAIN RARE CASES, CAN BE SEVERE. THEREFORE, YOU MUST FOLLOW THESE PRECAUTIONS:

- **DO NOT USE IF:**
  - YOU HAVE ALREADY HAD A REACTION TO A HAIRCOLOR PRODUCT.
  - YOU HAVE A SENSITIVE, ITCHY OR DAMAGED SCALP.
- IF YOU HAVE A TATTOO, THE RISKS OF AN ALLERGIC REACTION MAY BE INCREASED.
- PERFORM A SKIN ALLERGY TEST 48 HOURS BEFORE EACH USE OF THIS PRODUCT (SEE INSERT). REMEMBER TO BUY YOUR PRODUCT 2 DAYS AHEAD OF TIME.
- AVOID CONTACT OF THIS PRODUCT WITH EYES AND SKIN.
- IF PRODUCT GETS INTO EYES, RINSE IMMEDIATELY.
- WEAR GLOVES PROVIDED IN KIT.
- THOROUGHLY RINSE HAIR AFTER APPLICATION.
- DO NOT USE OVER COMPOUND HENNA OR PROGRESSIVE COLOR.
- WAIT AT LEAST 14 DAYS AFTER BLEACHING, RELAXING OR PERMING BEFORE COLORING.
- KEEP PRODUCT OUT OF THE REACH OF CHILDREN. DO NOT APPLY ON CHILDREN.

**CAUTION:** THIS PRODUCT CONTAINS INGREDIENTS WHICH MAY CAUSE SKIN IRRITATION ON CERTAIN INDIVIDUALS AND A PRELIMINARY TEST ACCORDING TO ACCOMPANYING DIRECTIONS SHOULD FIRST BE MADE. THIS PRODUCT MUST NOT BE USED FOR DYEING THE EYELASHES OR EYEBROWS; TO DO SO MAY CAUSE BLINDNESS.