



## **Naturally Misleading:**

Consumers' Understanding of  
"Natural" and "Plant-Derived"  
Labeling Claims



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Founded in 1899, the National Consumers League is America's pioneer consumer organization. Our mission is to identify, protect, represent, and advance the economic and social interests of consumers and workers.

NCL is your advocate when it comes to many consumer issues, including: Internet fraud, health care, sweatshops, e-commerce, migrant farmwork, electricity deregulation, consumer education, and financial services. To learn more about NCL's work in labeling and drug safety issues, visit us online at [www.nclnet.org](http://www.nclnet.org).

# Naturally Misleading

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As consumers increasingly choose to take charge of their health and manage their own medications and treatments, it is more important than ever for consumers to understand the claims made regarding drug products, dietary supplements, personal care products, and food items. Just because something is on the shelf at the grocery store or drug store does not render the product harmless. When taking drugs and dietary supplements, consumers must always be cautious of interactions with foods and medications and possible side effects, even if the product is labeled “natural.”

The commonly held belief that “natural” products come from nature may be giving consumers a false sense of security about their safety. While aging baby boomers have a desire to stay young and healthy through the use of “natural” or “plant-derived” products, they must understand that just because the products are labeled or advertised as “natural” does not guarantee that the product is safe or harmless for consumers or safer than similar products not bearing the “natural” label. Government agencies that regulate drugs, food, and personal care products have been warning consumers that “natural” is not synonymous with safe. But studies by the National Consumers League (NCL) show that the message may not be resonating with consumers. While consumers may think that when they buy “natural” they are buying unprocessed, pure, and gentle products, “natural” products can be very powerful and have serious side effects.

In a January, 2002 survey recently commissioned by NCL, 86 percent of the participants believed that products advertised or labeled as “natural” were safe.<sup>1</sup> Three out of four of those surveyed expected these “natural” products to contain at least 90 percent natural ingredients.<sup>2</sup>

NCL commissioned the survey to find out how Americans understand the claim of “natural” or “plant-derived” on various products, including drugs, dietary supplements, personal care products, cosmetics, and food items. The League also commissioned four focus groups, composed of women over age 45, to explore their views of products labeled “natural” or “plant-derived,” as an extension of past NCL research of this particular population segment and their use of dietary supplement products.

### ***The “Natural” Claim on Labels and in Advertising***

There has been much use of the term “natural,” and “plant-derived” on foods, drugs, dietary supplements, and personal care products. Such labeling and advertising attempts to communicate to consumers that their bodies naturally need this product, and it is therefore safe, harmless, and beneficial to overall health. The word “natural” on a label or in advertising brings to mind nature, and things that are pure, clean, and healthy; if it’s

natural, it must be the real thing. Some packaging has pictures of trees and flowers that lulls consumers into complacency without regard to possible side effects or harm. Over three-quarters of those surveyed believe that products labeled “natural” are made without chemical additives and are pure or wholesome.<sup>3</sup> In the focus groups, most respondents were positively predisposed to products with the “natural” claim and described “natural” products as gentle and pure.<sup>4</sup> Consumers choose some products over others because they prefer the natural alternative. When consumers compare a product labeled “natural” with similar products that are not, 74 percent believe the natural product is safer to use long term, 76 percent believe it has fewer and less serious side effects, and 70 percent believe it is less likely to cause interactions with medications.<sup>5</sup> When the focus groups were questioned about a “natural” labeled product, many participants persisted in attributing safety benefits based on the “natural” claim. “If it’s natural, it must be good,” stated one participant.<sup>6</sup>

A 1999 Reader’s Digest/TNS Intersearch survey showed that 66 percent of consumers who used alternative treatments such as herbal supplements did so because they simply prefer the “natural method.”<sup>7</sup> A survey by Prevention magazine reported that 36 percent of consumers will choose herbal products over prescription drugs and 48 percent of consumers will use herbals instead of over-the-counter (OTC) drugs. Why? Forty-seven percent of those choosing herbals over OTC and 43 percent of those choosing herbals over prescription drugs do so because they prefer “natural” products.<sup>8</sup>

### ***Consumer Understanding of the Natural Claim***

The NCL survey revealed that the majority of the participants (64 percent) are very or somewhat confident that the claim of “natural” accurately describes the ingredients and processes for that product.<sup>9</sup> Many consumers are turning to “natural” products because they believe the products will improve their health. Eighty percent of those surveyed believe that “natural” products are “good for me,” and nearly 70 percent believe that the “natural” product is something their body needs; and if they use it, their overall health will improve.<sup>10</sup> As one participant of the focus group stated, “I tend to idealize ‘natural’ products.”<sup>11</sup>

But a product labeled “natural” may not always be what your body needs for optimal health. The California Department of Human Services found in a random sample of herbal stores that nearly a third of these “natural” remedies contained either heavy metals (such as lead, arsenic, and mercury) or undeclared pharmaceuticals.<sup>12</sup> Products containing unsafe levels of heavy metals or prescription drugs could be disastrous to unsuspecting consumers purchasing a “natural” product.

There is a strong assumption that products labeled or advertised as “natural” are indeed natural. Seventy-five percent of consumers polled expected at least 90 percent of the ingredients in “natural” labeled products to be natural.<sup>13</sup> Yet, studies show this may not be the case. Anso Comfort Capsules, promoted as a “natural” herbal dietary supplement useful for treating a wide variety of illnesses, including high blood pressure and high cholesterol, were found to contain the undeclared prescription drug Chlordiazepoxide.<sup>14</sup> Chlordiazepoxide is an addictive controlled substance used for anxiety and as a sedative, and can be dangerous if taken without medical supervision. The distributor recalled the product and consumers were warned to immediately stop using it.<sup>15</sup>

### ***Government Regulation of the Claim of “Natural”***

For consumers to understand what the “natural” label says about a drug, dietary supplement, personal care product, or food item, consumers need to understand how the government regulates the claim of “natural.” The government agencies regulating the labeling and advertising of drugs, dietary supplements, personal care products, and food have not issued much guidance on the use of “natural” on labels and advertising of these products. Because there is a lack of consensus on what the term “natural” actually means for a product, there has been little regulation regarding the term. There are no regulations or guidelines regarding the use of “plant-derived” claims on these products.

If consumers are not familiar with government guidelines regarding use of the term “natural,” they may be confused about what the term implies. When a consumer goes to the grocery, health food, or drug store, an array of products claim to be “natural.” While the term “natural” is defined by the government for meat and poultry products, it is not defined for use on drugs, personal care products, dietary supplements, and other food products. Consumers may see the label on one product (meat and poultry) and think the same underlying concepts apply to the natural label on another product (cosmetics). A majority of those surveyed were not familiar with how the government regulates the claim of “natural.”<sup>16</sup> Focus group participants unanimously agreed that there was a need for greater regulation of the “natural” products regarding labeling, advertising, and industry standards. Consumers in the focus groups were interested in regulations that would clarify the definition of natural, and develop standards regarding the content of “natural” products. Such standards would require “natural” products to declare on the label the percent of natural ingredients, the presence of preservatives, antibiotics, chemicals, and other additives and the degree of processing.<sup>17</sup>

## **Foods**

For meat and poultry items, the United States Department of Agriculture (USDA) allows the use of the term “natural” only if the product contains no artificial ingredients, coloring ingredients, or chemical preservatives, and if the product and its ingredients are not more than minimally processed.<sup>18</sup> The label must explain the use of the term natural, such as “no added coloring” or “artificial ingredients,” or “minimally processed.”<sup>19</sup> The “natural” label does not cover animal production practices.<sup>20</sup> Even though a meat or poultry product bears the “natural” label, the animal itself could have been raised using antibiotics or growth stimulants.

For other food products, the Food and Drug Administration (FDA) regulates the use of “natural flavoring” on labels. For foods in which the only flavor is a natural flavor, the product can be labeled “natural strawberry flavor.” Natural flavor is defined as the essential oil, extract, or essence that contains the flavor derived from a spice, fruit, vegetable, herb, or other product whose function is flavoring.<sup>21</sup>

Many food items are now labeled “organic.” “Natural” is not the same as “organic.” While “natural” is not defined by the FDA for food products, the USDA has published a final rule for the production, handling, and processing of organically grown agricultural products.<sup>22</sup> According to the final rule, the organic production of food involves integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balances and conserve biodiversity.<sup>23</sup>

## **Drugs**

FDA does not specifically define or regulate the use of the claim “natural” or “plant-derived” for drugs, prescription or over-the-counter. Generally, drug product labels or advertising cannot make false or misleading statements.

## **Dietary Supplements**

FDA, which regulates the claims made on the labeling of dietary supplements, does not define or standardize the use of the word “natural” on dietary supplements. It also does not regulate the safety and efficacy (whether a product works or not). Generally, FDA prohibits labeling that is false or misleading. The Federal Trade Commission (FTC) has jurisdiction over the advertising of dietary supplement products. The FTC will take action against false, deceptive, unsubstantiated, or misleading advertising. While the FTC has not specifically challenged the claim of “natural” or “plant-derived” on a dietary supplement, there have been cases in which the manufacturer of a dietary supplement that was that was labeled as a “natural” remedy had been

charged with making unsubstantiated claims. Some examples of such cases are reported below.

## **Personal Care Products /Cosmetics**

The FDA does not define or regulate the use of the word “natural” on personal care or cosmetic products. FDA’s Office of Cosmetics and Colors has, however, produced consumer information regarding the “natural” claim for personal care products. A 1994 unpublished survey by the FDA Office of Cosmetics and Colors found that nearly half of those surveyed felt that a personal care product claiming to be natural should contain all natural ingredients.<sup>24</sup> While “natural” implies that ingredients are derived from plants or animal products, as opposed to being produced synthetically, it is not necessarily true that products containing natural ingredients are good for the skin.<sup>25</sup> If one has a certain plant or animal allergy, he or she could experience the same allergic reaction to cosmetics containing those ingredients. For example, Lanolin, extracted from sheep wool, is a common allergen and an ingredient in many moisturizers.<sup>26</sup> Additionally, some manufacturers of “natural” cosmetics use naturally occurring vitamins E and C as preservatives.<sup>27</sup> The topical vitamin E is a potent sensitizer, however, and can produce an allergic reaction.<sup>28</sup> Even the plants that are used in cosmetics are not necessarily pure and clean; they may be contaminated with bacteria, pesticides, and chemical fertilizer.<sup>29</sup> In addition, “all natural” cosmetics are likely to have an unusually short shelf life if they contain plant-derived substances conducive to microbial growth.<sup>30</sup>

### ***Examples of “Natural” and “Plant-derived” Claims***

Set forth below are examples of products claiming to be “natural” or “plant-derived” that were not necessarily all natural, safe, or effective. In some cases, the FDA and FTC have taken actions against manufacturers of “natural” products for a variety of reasons.

#### **“Plant-derived” Products**

Just because a product is derived from a plant does not mean it is safe:

- In April 2001 FDA warned consumers that consumption of botanical products containing aristolochic acid, which is found primarily in the plant *Aristolochia*, had been associated with kidney damage and some types of cancer.<sup>31</sup> FDA advised consumers to immediately discontinue use of any botanical product containing *Aristolochia* acid.<sup>32</sup> A botanical product is defined as containing vegetable matter and may include plant materials.
- When an herbal tea containing senna, aloe, buckthorn and other plant-derived laxatives was consumed

in excessive amounts it was found to cause diarrhea, vomiting, nausea, stomach cramps, chronic constipation, fainting, and perhaps death.<sup>33</sup> As a result, the FDA advised consumers to follow package directions carefully.<sup>34</sup> The FDA considered requiring the manufacturer to place a warning about the product's potential side effect on the product's label.<sup>35</sup>

## **100% Natural?**

Products claiming to be all “natural” or “plant-derived” may include more than just natural ingredients or plant products.

- The label on Nature's Nutrition Formula One stated that it was an “all natural nutritional supplement” containing ma huang, and kola nut, two naturally occurring sources of ephedrine and caffeine.<sup>36</sup> To provide added stimulation and keep customers coming back for more, the manufacturer decided to substitute pharmaceutical-grade ephedrine and caffeine for the ma huang and kola nut extracts.<sup>37</sup> The manufacturer repeatedly denied to the FDA that the company ever added synthetic chemicals to Formula One.<sup>38</sup> FDA received various complaints of serious injuries and deaths associated with Formula One.<sup>39</sup> A criminal investigation by FDA eventually landed the manufacturer in jail for 21 months and cost his company more than \$4.7 million in fines and fees.<sup>40</sup>
- A study has showed that Cenestin, a hormone replacement therapy claiming to be “100% plant derived,”<sup>41</sup> is actually approximately 65 percent plant-derived.<sup>42</sup> The study broke Cenestin tablets down into two samples, one of estrone and one of the remaining estrogens (which amounted to half of the estrogens in each tablet).<sup>43</sup> The study showed that the estrone sample analyzed as 100 percent plant derived, while the other sample of estrogens analyzed as 30 percent plant derived, and the rest of the sample was derived largely from fossil sources such as petrochemical feedstock.<sup>44</sup>

## **Safety and Effectiveness Not Proven**

“Natural” products are not necessarily safer or more effective than conventional products.

- FDA sent a warning letter to the manufacturer of “The Natural Dentist Herbal Mouth and Gum Therapy Daily Oral Rinse” because of the failure to submit effectiveness and safety data prior to marketing of the product.<sup>45</sup>
- A transdermal weight-loss patch was advertised as a “healthy, simple, and natural way to help you lose and control weight.”<sup>46</sup> FDA issued a warning letter to the marketer of the patch because it did not have

an approved new drug application.<sup>47</sup> The new skin-delivery system required evidence of effectiveness, which the manufacturer of the product had not supplied to the FDA, before the product could be marketed.<sup>48</sup>

- The dietary supplement Life Plus Colloidal Silver was promoted as an “amazing natural alternative to antibiotics . . . proven to be useful against many different infections.”<sup>49</sup> FDA issued the manufacturer a warning letter because the product was being promoted as a drug and the FDA had no information that the product was safe and effective.<sup>50</sup>

### ***Misleading Claims on “Natural” Products (FTC Actions)***

- The advertisements for “God’s Recipe” claimed it was a “natural,” safe alternative for treating Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder (ADD/ADHD).<sup>51</sup> The ads exploited parents’ fears of prescription drugs like Ritalin. The FTC charged that the claim of curing, preventing, and treating ADD and ADHD, and the claim of “God’s Recipe” as an effective alternative treatment to prescription drugs like Ritalin, were unsubstantiated.<sup>52</sup> The FTC has found that parents whose children suffer from chronic disorders may find it especially hard to resist advertisements for dietary supplements that are promoted as safe, natural alternatives to prescription drugs for children.<sup>53</sup>
- Herbal Ecstasy, advertised as a “100% natural and absolutely safe” herbal high with no side effects, had as its main ingredient the herb ephedra, a botanical source of ephedrine alkaloids that can cause dangerous effects on the nervous system and heart.<sup>54</sup> Since the product was not “absolutely safe” and could cause side effects, the FTC charged that the claims made by Ecstasy were false or misleading and unsubstantiated.<sup>55</sup>
- Essiac Tea, a mixture of four herbs (burdock root, sheep sorrel, rhubarb root, and slippery elm bark), was advertised as a “natural” health remedy and therapy.<sup>56</sup> Implying that scientific proof, including clinical trials and tests, demonstrated its effectiveness in the mitigation, treatment, prevention, and cure of cancer.<sup>57</sup> FTC charged that the advertising was false and misleading because scientific proof, including clinical trails and tests, did not demonstrate that the tea was a cancer cure.<sup>58</sup>

### ***Consumer Tips***

As consumers navigate the marketplace of “natural” products and try to decide what is best for their health, they should not automatically assume “natural” is always best. They should remember that not all things natural

are safe. For example, poisonous mushrooms, found in nature, are deadly if eaten. Poison oak, ivy, and sumac often cause serious rashes and many people are allergic to natural foods such as peanuts, shellfish, strawberries, and even avocados. Moreover, products promoted as natural can be pharmacologically active and quite potent.

Here are some tips for consumers as they decipher the “natural” claims and labels:

- Understand the label. Just because a product says it’s “natural” or “plant-derived” does not necessarily mean it’s safe.
  - Talk with your healthcare provider. Always check with your physician or pharmacist about all medications and dietary supplements you are taking.
  - Be aware of possible interactions between “natural” dietary supplements and foods and drugs, prescription or over-the-counter.
  - Be a savvy consumer. Ask yourself if the “natural” claim is just advertising or hype. Is there an explanation of the ingredients/origins of the product?
  - Compare similar products. Compare a product that bears the “natural” label with a similar product that does not bear such a label. Are the ingredients/processes the same or different?
  - Check ingredient lists carefully. Are there any ingredients that may be harmful? If you are unsure, check with a health professional.
  - Read and follow product instructions carefully.
  - Research products before you use them.
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## ENDNOTES

- <sup>1</sup> Naturally Labeled Products – Wave 1, January 3, 2002 at 9 (Survey results prepared by Caravan, ORC International for National Consumers League).
- <sup>2</sup> *Id.* at 2.
- <sup>3</sup> *Id.* at 9.
- <sup>4</sup> Consumer Research on “Natural” Claims, A Qualitative Report, January 2001 at 3 (Report on Focus Groups, Prepared by Zimmerman Associates).
- <sup>5</sup> Naturally Labeled, *supra* note 1, at 4.
- <sup>6</sup> Consumer Research, *supra* note 4, at 9.
- <sup>7</sup> Roller, “Pharmacist’s Role Has Become Key Factor in Consumers Healthcare Decisions, Survey Says,” *Drug Store News*, Sept. 27, 1999.
- <sup>8</sup> *Prevention Magazine*, Consumer Use of Dietary Supplements, at 39 (1999).
- <sup>9</sup> Naturally Labeled, *supra* note 1, at 73.
- <sup>10</sup> Naturally Labeled, *supra* note 1, at 9.
- <sup>11</sup> Consumer Research, *supra* note 4, at 5.
- <sup>12</sup> Ko, “Adulterants in Asian Patent Medicines,” 339 *New Eng. J. of Med.*, Sept. 17, 1998 (letter to the editor).
- <sup>13</sup> Naturally Labeled, *supra* note 1, at 2.
- <sup>14</sup> “Anso Comfort Capsules Recalled by Distributor: Ingredient Poses Danger if Not Immediately Supervised,” *FDA News Release*, February 13, 2001.
- <sup>15</sup> *Id.*
- <sup>16</sup> Naturally Labeled, *supra* note 1, at 75.
- <sup>17</sup> Consumer Research, *supra* note 4, at 13.
- <sup>18</sup> U.S. Dept. of Agriculture, Policy Memo 055, November 22, 1982 (subject: natural claims).
- <sup>19</sup> *Id.*
- <sup>20</sup> U.S Dept. of Agriculture, Office of Policy, Program Development and Evaluation, Labeling and Consumer Protection Staff, Natural and Organic Claims, March 8, 1999 (letter to producers regarding natural and organic claims).
- <sup>21</sup> 21 CFR Secs. 101.22(a) (3), (g) (3) (2001).
- <sup>22</sup> 7 CFR Part 205 (2001).
- <sup>23</sup> *Id.*
- <sup>24</sup> Lewis, “Clearing Up Cosmetic Confusion,” *FDA Consumer*, May-June 1998.
- <sup>25</sup> *Id.*
- <sup>26</sup> “On the Teen Scene, Cosmetics and Reality,” *FDA Consumer*, May 1994.
- <sup>27</sup> Stehlin, “Cosmetic Safety: More Complex Than at First Blush,” *FDA Consumer*, November 1991.
- <sup>28</sup> *Id.*
- <sup>29</sup> *Id.*
- <sup>30</sup> “Shelf Life-Expiration Date,” Office of Cosmetics Fact Sheet, *FDA*, March 9, 2000.
- <sup>31</sup> *FDA Consumer Advisory*, “FDA Warns Consumers to Discontinue Use of Botanical Products That Contain Aristolochic Acid,” April 11, 2001.
- <sup>32</sup> *Id.*
- <sup>33</sup> Kurtzweil, “Dieter’s Brew Makes Tea Time A Dangerous Affair,” *FDA Consumer*, July-August 1997.
- <sup>34</sup> *Id.*
- <sup>35</sup> *Id.*
- <sup>36</sup> Lewis, “Dietary Supplement Maker Fined Twice What Company Profited,” *FDA Consumer*, January-February 2001.
- <sup>37</sup> *Id.*
- <sup>38</sup> *Id.*
- <sup>39</sup> *Id.*
- <sup>40</sup> *Id.*
- <sup>41</sup> “Frequently Asked Questions on Cenestin,” [www.cenestin.com](http://www.cenestin.com), Jan. 2002 (Web site).
- <sup>42</sup> Hayes and Sylva, “Measurement of Carbon-14 Can Reveal Mixtures of Natural Fossil-Derived Product in Pharmaceutical Preparations,” Programme and Book of Abstracts (presented at the 9<sup>th</sup> World Congress of Gynecological Endocrinology, Hong Kong, Dec. 2-5, 2001) (Study conducted at Woods Hole Oceanographic Institution).
- <sup>43</sup> *Id.*
- <sup>44</sup> *Id.*
- <sup>45</sup> *FDA Warning Letter* from Douglas Ellsworth, District Director, New Jersey District Office, to

William Stern, President, Woodstock Natural Products (Dec. 11, 1997).

<sup>46</sup> Kurzweil, “How to Spot Health Fraud”, FDA Consumer, November-December 1999.

<sup>47</sup> Id.

<sup>48</sup> Id.

<sup>49</sup> FDA Warning Letter from David Horowitz, Office of Compliance, Center for Drug Evaluation and Research, to Mr. Patrick Greenfield, U.S. Medicare (March 9, 2001).

<sup>50</sup> Id.

<sup>51</sup> ”Multi-level Marketing Company to Settle FTC Charges That It Made Unsubstantiated Claims That Its ‘God’ Recipe’ Dietary Regimen Could Cure ADD/ADHD,” FTC Release, December 8, 1998.

<sup>52</sup> Id.

<sup>53</sup> Kurtzweil-Walter, “Promotions for Kid’s Dietary Supplements Leave Sour Taste,” FTC Consumer Features, Bureau of Consumer Protection, May 2000.

<sup>54</sup> “Claims that Herbal Ecstasy is Absolutely Safe and Will Not Cause Side Effects are False, FTC Says,” FTC Release, July 29, 1997.

<sup>55</sup> Id.

<sup>56</sup> In the Matter of Natural Heritage Enterprises, No. C-3941 (Fed. Trade Com., filed May 16, 2000) (complaint).

<sup>57</sup> Id.

<sup>58</sup> Id.