I. INTRODUCTION AND SUMMARY

The staff of the Federal Trade Commission’s (“FTC” or “Commission”) Bureau of Consumer Protection, Office of Policy Planning, and Bureau of Economics (collectively, “FTC staff”) appreciates the opportunity to respond to the Food and Drug Administration’s (“FDA”) Notice of Request for Comments Related to its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century. The FDA has requested public comments regarding the current use of human drug and biological products labeled as homeopathic, as well as the agency’s regulatory framework for such products.

In general, under the Food, Drug, and Cosmetic Act, drug products must be approved by FDA or generally recognized as safe and effective. However, under the current regulatory
framework for homeopathic drugs,\(^4\) as set forth in its 1988 Compliance Policy Guide,\(^5\) FDA does not require that OTC homeopathic drugs comply with these requirements if they satisfy certain conditions, including that the label of such products contain an indication for use.

For the reasons discussed below, the FTC staff recommends that the FDA reconsider its regulatory framework for homeopathic medicines. The FTC staff is concerned that the FDA’s existing regulatory framework may conflict with the Commission’s advertising substantiation policy in ways that may harm consumers and create confusion for advertisers.\(^6\) These concerns are bolstered by the results of FTC staff research exploring consumers’ understanding and perceptions of homeopathy and homeopathic drugs. As explained below, this evidence suggests that a significant percentage of consumers do not understand homeopathy, how the FDA regulates homeopathic drugs, or the level of scientific evidence supporting homeopathic claims.

II. INTEREST AND EXPERIENCE OF THE FTC

The FTC’s authority over disease and other health-related claims comes from Sections 5 and 12 of the FTC Act. Section 5, which applies to both advertising and labeling, prohibits unfair or deceptive acts or practices in or affecting commerce, such as the deceptive advertising or labeling of over-the-counter (OTC) drugs.\(^7\) Section 12 prohibits the dissemination of false

---

\(^4\) A homeopathic drug is any drug that is “labeled as being homeopathic which is listed in the Homeopathic Pharmacopeia of the United States (HPUS), an addendum to it, or its supplements.” Homeopathy is based on the view that disease symptoms can be cured by small doses of substances that produce similar symptoms when provided in large doses to healthy people. See FDA’s Compliance Policy Guide (CPG) 400.400 entitled “Conditions Under Which Homeopathic Drugs May be Marketed,” 53 FR 21728, June 9, 1988, available at www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm.

\(^5\) Id.

\(^6\) In addition to providing these comments, the FTC staff of the Division of Advertising Practices is holding a public workshop on September 21, 2015 to hear various points of view on the advertising of homeopathic medicine. See FTC to Host September Workshop in Washington, DC, to Examine Advertising for Over-the-Counter Homeopathic Products, available at https://www.ftc.gov/news-events/press-releases/2015/06/ftc-host-september-workshop-washington-dc-examine-advertising.

advertisements in or affecting commerce of food, drugs, devices, services, or cosmetics.\footnote{Federal Trade Commission Act, 15 U.S.C. § 52.} Under these provisions, companies must have a reasonable basis for making objective claims, including claims that a product can treat specific conditions, before those claims are made.\footnote{See Advertising Substantiation Policy Statement, appended to \textit{Thompson Medical Co.}, 104 F.T.C. 648, 839 (1984), aff’d, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987).} The FTC devotes significant enforcement and educational resources to protect consumers from unsubstantiated and misleading health claims in advertising for OTC products.

There is considerable overlap between FDA’s and FTC’s jurisdiction. For over 40 years, the FTC and the FDA have worked together collaboratively to regulate the marketing of OTC products. With regard to OTC drug products, pursuant to a 1971 Memorandum of Understanding between the two agencies, the FDA focuses on product labeling while the FTC focuses on product advertising.\footnote{See Working Agreement Between the FTC and FDA, 3 Trade Reg. Rep. ¶ 9851 (CCH) (1971).} With the exception of OTC homeopathic drugs discussed below, the regulatory approach of the two agencies has been remarkably consistent.

\section*{III. FACTUAL AND REGULATORY BACKGROUND}

\subsection*{A. FDA Authority}

All articles that meet the definition of a “drug” under the Food, Drug, and Cosmetic Act (“FD&C Act”)\footnote{21 U.S.C. § 321(g)(1)(A)-(C).} – including homeopathic drugs – are subject to regulation under the FD&C Act. Specifically, the FD&C Act requires that drugs cannot be sold until they are recognized among qualified experts to be safe and effective. Despite this requirement, homeopathic drugs have never been regulated under the FD&C Act like other conventional drugs.

In an effort to bring all drugs into compliance with the FD&C Act, the FDA initiated a rulemaking in 1972 to determine which OTC drugs were generally recognized among qualified experts as safe and effective and not misbranded, under prescribed, recommended, or suggested...
conditions of use. As part of that rulemaking, the FDA deferred review of drugs labeled as homeopathic “due to the uniqueness of homeopathic medicine” and stated that FDA would review them as a separate category at a later time.\textsuperscript{12} To date, FDA has not reviewed this class of products for efficacy.\textsuperscript{13}

Instead, in 1988, the FDA issued Compliance Policy Guide (“CPG”) 400.400 entitled “Conditions Under Which Homeopathic Drugs May be Marketed,” which permitted the manufacture and distribution of homeopathic products without FDA approval.\textsuperscript{14} Under the CPG, which is still in effect, the FDA permits a company to sell OTC homeopathic products without demonstrating their efficacy and—unlike both non-homeopathic drugs and dietary supplements—to include claims in their packaging about treating specific conditions as long as the conditions are “self-limiting” and not chronic. The CPG also requires that the labeling of homeopathic drugs display an indication for use.

B. FTC Authority

The FTC’s well-established position on advertising substantiation was first announced in 1972 and has been repeatedly reaffirmed.\textsuperscript{15} For health, safety, or efficacy claims, the FTC has generally required that advertisers possess “competent and reliable scientific evidence,”\textsuperscript{16} defined as “tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield

\textsuperscript{12} 37 Fed. Reg. 9464, 9466 (May 11, 1972); see also 80 Fed. Reg. 16327, 16328 (Mar. 27, 2015).
\textsuperscript{13} 80 Fed. Reg. at 16328.
\textsuperscript{15} See Pfizer, 81 F.T.C. 23 (1972); POM Wonderful LLC v. FTC, 777 F.3d 478, 490 (D.C. Cir. 2015).
\textsuperscript{16} See POM Wonderful, 777 F.3d at 505 (the baseline requirement for health-related claims independently bars any representations unless supported by competent and reliable scientific evidence that is sufficient to substantiate that the representations are true).
accurate and reliable results."\(^{17}\) Competent and reliable scientific evidence may take different forms depending on the type of claim being made. For some claims, the substantiation required may be one or more well-designed human clinical studies.\(^{18}\) Neither the FTC Act, nor any FTC rule or policy statement, exempts advertising claims for homeopathic drugs from these standards.

IV. THE FDA REGULATORY FRAMEWORK MAY HARM CONSUMERS AND CAUSE CONFUSION FOR ADVERTISERS

A. Potential Conflict Between FDA’s Regulatory Framework and FTC’s Advertising Substantiation Policy

The FDA broadly defines labeling to include any article that accompanies a product. This can include websites and, under certain circumstances, advertising. Likewise, advertising is broadly interpreted under the FTC Act. Accordingly, the requirement that labeling for homeopathic drugs display an indication for use, even when the product has not been demonstrated to be efficacious for that indication, creates a potential conflict with the FTC’s requirement that health claims be substantiated by competent and reliable scientific evidence. This potential conflict does not exist with respect to dietary supplements or non-homeopathic OTC drugs because both FTC and FDA law require that advertisers have substantiation to support efficacy claims for those products.

This potential conflict could be eliminated in one of three ways. First, the FDA could withdraw the CPG, thereby subjecting homeopathic drugs to the same regulatory requirements as other drug products. Second, the FDA could eliminate the requirement in the CPG that an indication appear on the labeling. Companies could still include an indication on the label, and

\(^{17}\) See, e.g., Brake Guard Prods., Inc., 125 F.T.C. 138 (1998)

\(^{18}\) Removatron Int’l Corp., 111 F.T.C. 206 (1988), aff’d, 884 F.2d 1489 (1st Cir. 1989) (requiring “adequate and well-controlled clinical testing” to substantiate claims for hair removal product); Thompson Medical Co., 104 F.T.C. at 826 (requiring two well-controlled clinical studies to substantiate certain analgesic drug claims); see also, generally, POM Wonderful, 777 F.3d at 498 (approving the imposition of a randomized controlled trial requirement for disease claims).
would likely do so, but it would not be a specific requirement of the FDA’s discretionary non-enforcement policy. As it stands, when an advertiser follows the CPG requirement to provide an indication on its product label without competent and reliable scientific evidence to support it, the advertiser violates FTC law which, contrary to the CPG, requires such evidence for any health claims such as indications. Finally, given that the CPG is a discretionary enforcement policy, a third way to eliminate the potential conflict discussed above would be for the FDA to require that any indication appearing on the labeling be supported by competent and reliable scientific evidence.

B. Related Conflicts and Problems Caused by the CPG

In addition to creating a potential conflict between FTC and FDA law, the CPG may lead to confusion for both advertisers and consumers, especially within the context of industry self-regulation of advertising. The CPG may also create a loophole by which manufacturers can take advantage of the less stringent requirements for homeopathic drugs, to the possible detriment of consumers.

The National Advertising Division (“NAD”) of the Council of Better Business Bureaus is a self-regulatory body that attempts to resolve disputes between advertisers by providing voluntary recommendations on how to address misleading advertising. Pursuant to NAD procedures, one advertiser can file a claim against another advertiser to challenge advertising it believes to be false or deceptive. In addition, the NAD itself can raise advertising issues sua sponte as part of its routine monitoring program. To the extent that an advertiser declines to follow the NAD’s recommendation, the NAD can refer the matter to the FTC.

In at least one prior instance, the potential conflict between the CPG and the FTC’s substantiation requirement has complicated an NAD inquiry regarding advertising for a
homeopathic drug. In 2007, as part of its routine monitoring program, the NAD requested substantiation for several claims Similasan Corporation made in its advertising for its Earache Relief Ear Drops.\textsuperscript{19} In its decision, the NAD recommended that the company discontinue its claim that the product “Relieves Pain, Soothes & Calms, [and is] Safe for Use with Antibiotics” because the advertiser could not provide competent and reliable evidence to support the claim.\textsuperscript{20} Similasan responded in an “Advertiser’s Statement” that it was not required to have such evidence because the CPG did not require it.\textsuperscript{21} Of greater concern, however, was Similasan’s comment that the NAD, in its decision, appeared to be “imposing a standard of proof which is imposed neither by the FDA\textbf{ nor the Federal Trade Commission.”}\textsuperscript{22}

As shown by Similasan’s comment, the FDA’s current regulatory framework could lead homeopathic drug advertisers to incorrectly assume, or at least to argue, that the FTC does not require competent and reliable scientific evidence to support the advertisers’ efficacy claims. To the contrary, in several joint warning letters with FDA, the Commission staff has stated that the FTC Act requires competent and reliable scientific evidence to support claims made for products labeled as homeopathic.\textsuperscript{23} Nevertheless, in the past, Commission staff has been reluctant to pursue cases against OTC homeopathic products because the Commission’s traditional remedies, such as requiring that health claims be supported by competent and reliable scientific evidence, could create a potential conflict with FDA policy under the CPG.

\textsuperscript{19} See National Advertising Division Case Report #4650 (04/02/07), Similasan Corporation USA, Earache Relief Ear Drops, Exhibit (Ex.) A.
\textsuperscript{20} Id. at 5.
\textsuperscript{21} Id. at 6.
\textsuperscript{22} Id. (emphasis added).
Overall, advertisers who mistakenly believe that compliance with the CPG exempts them from compliance with the FTC Act’s substantiation requirement may unwittingly subject themselves to liability for injunctive and monetary remedies in an FTC enforcement proceeding. At the very least, the potential conflict between the FDA’s homeopathic CPG and the FTC’s substantiation requirement creates enforcement challenges for the FTC. This conflict also may create uncertainty for advertisers and consumers, which may substantially harm the interests of both.

Another concern is that the FDA’s policy for homeopathic products may encourage some companies to attempt to skirt FDA regulations by marketing their dietary supplement products as homeopathic drugs. A manufacturer can label a product as “homeopathic” when it contains both homeopathic ingredients and other ingredients such as dietary supplements, if they designate the latter as inactive ingredients in the substance.24 A manufacturer could easily take advantage of the protective umbrella created by the FDA’s current regulatory framework, by simply labeling the product “homeopathic” and arguing that the product’s efficacy claims need not be substantiated.

---

24 The CPG states that “drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products.” However, a difficulty arises when companies include “non-homeopathic” active ingredients in the “inactive ingredient” list. In that case, it is up to FDA to show that these “inactive” ingredients are, in fact, active ingredients. An “active ingredient” is defined under 21 C.F.R. §§ 201.66(b)(2) and 210.3(b)(7)) as any component that is intended to furnish pharmacological activity or direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. There are a wide variety of inactive ingredients, and it is possible for companies to claim that their questionable “inactive” dietary supplements act as emulsifiers or preservatives. If the FDA cannot disprove this purpose, the product can be considered homeopathic.
V. FTC STAFF’S CONCERNS ARE BOLSTERED BY RESEARCH ON CONSUMER PERCEPTIONS ABOUT HOMEOPATHY AND HOMEOPATHIC MEDICINE

The FTC staff has conducted copy tests and focus groups concerning consumers’ understanding of homeopathy and homeopathic remedies. This research, combined with additional observations regarding how homeopathic remedies are marketed, exacerbates the concerns raised above, because our research suggests that a significant percentage of consumers do not understand the nature of homeopathic products, how they are regulated, or the level of substantiation to support claims for those products.

A. Focus Group Results

The FTC staff worked with Shugoll Research to set up focus groups in order to explore consumer understanding of various non-prescription products including conventional, herbal, and homeopathic products. Market research was conducted to explore the understanding and knowledge of non-prescription products among two key consumer segments – general adults (including parents and non-parents) and parents. The overall objective of the focus groups was to determine the extent to which consumers understand the differences among conventional, herbal, and homeopathic non-prescription products.

Two focus groups were conducted in Baltimore, Maryland in late 2010. One focus group included eight adults while the other included eight parents. With input from the FTC staff, Shugoll developed two screening questionnaires to recruit these focus group respondents.

26 Id.
27 Id. The focus group report employed a qualitative research methodology rather than a quantitative one. See id. at 5. As stated in the report, qualitative research methodologies seek to develop directions rather than quantitatively precise or absolute measures, and the results are used to generate hypotheses for decision making and further testing rather than to provide a basis to make generalizations about the population under study. Id. Accordingly, the FTC employed the findings developed from this focus group to undertake the copy test discussed in Section V.B. below.
28 Ex. B at 3.
29 Id.
During the focus groups, the respondents were asked to discuss, among other things, the differences among conventional, herbal, and homeopathic products.\textsuperscript{30}

Among focus group participants, adults and parents were likely to group or categorize products in a number of ways including conventional versus “natural” products, and awareness of non-prescription cold products was very high.\textsuperscript{31} Adults tended to keep on hand several products designed to treat cold symptoms, and these products were primarily conventional. Additionally, parents were likely to have fever-reducing products in their medicine cabinets in addition to those designed to treat cold symptoms.\textsuperscript{32} While adults and parents clearly differentiated conventional non-prescription products from non-conventional products, most struggled when asked to distinguish between herbal and homeopathic products.\textsuperscript{33} Most parents and adults associated homeopathic products with natural or “non-chemical” products.\textsuperscript{34}

Many adults and parents did not readily differentiate between evidentiary requirements and federal regulatory requirements for different types of products.\textsuperscript{35} While they generally believed that manufacturers of conventional non-prescription products were required to support their claims with scientific evidence, they had varying opinions regarding the evidentiary requirements and federal oversight for herbal and homeopathic products, with some parents and adults indicating there were no requirements, others insisting there must be some governmental oversight, and still others who were unsure but hopeful that there were requirements.\textsuperscript{36}

\begin{flushleft}
\textsuperscript{30} Id.
\textsuperscript{31} Id. at 9.
\textsuperscript{32} Id.
\textsuperscript{33} Id. at 17.
\textsuperscript{34} Id.
\textsuperscript{35} Id. at 19.
\textsuperscript{36} Id.
\end{flushleft}
The focus group results also suggested that there is a poor understanding of the principles underlying homeopathic products. Most adults and parents equated homeopathic products with natural and/or home remedies, and even those who had purchased homeopathic products were unfamiliar with the principles underlying homeopathy. When those principles were explained to adults and parents in the group, they found them confusing; some parents were motivated by the relatively few side effects of homeopathic products, while the explanation of how homeopathy was supposed to work made other parents and adults question the effectiveness of the products. Furthermore, most adults and parents were more likely to continue to use the conventional non-prescription products with which they were familiar and unlikely to purchase homeopathic products without an express recommendation from a trusted source due to their skepticism about the effectiveness of such products.

As explained in the focus group report, while the parents and adults who participated in the focus group had a high degree of familiarity and understanding of conventional non-prescription products, they did not understand what “homeopathic” means or how homeopathy works. In fact, the parents and adults tended to group all non-conventional products together, including homeopathic products, into a single category, using the terms “natural,” “herbal,” and “homeopathic” interchangeably. More importantly, upon learning more about the theory of homeopathy after Shugoll representatives explained the principles behind it to them, many participants became skeptical about its efficacy and more guarded about using it. These results suggest that many consumers may choose homeopathic products based on incorrect and

37 Id. at 23.
38 Id.
39 Id. at 24.
40 Id. at 25-26.
41 Id. at 28.
42 Id.
43 Id.
incomplete information about them. When given additional information, however, they looked
more critically at homeopathic treatments and had a better basis on which to evaluate them in
comparison to other remedies.44

B. Copy Test Results

Dr. Manoj Hastak, a professor of marketing at the Kogod School of Business at American
University and a consultant for the FTC, designed a research study to investigate what was
communicated to consumers upon exposure to a package of one of three homeopathic drug
products.45 The study was designed to address several targeted questions and was conducted
online via an online panel.46 Respondents were invited to complete a screening questionnaire
and were offered an incentive of $3 if they were eligible for and participated in the study.47
Depending on their eligibility, respondents were first assigned to one of ten conditions. These
ten conditions consisted of three different versions of a Similasan product claimed to relieve
cold-related symptoms in children aged 2-12, three different versions of a Boiron product called
Oscillococcinum claimed to relieve flu symptoms, and four different versions of a Hylands
product called Arnica claimed to relieve pain.48

The three versions of the Similasan product consisted of the original product available in
the market at the time, a version that was identical to the original product available in the market
except that the word “HOMEOPATHIC” at the top of the package front panel was made larger
and more prominent, and a third version that was identical to the original product except that the
words “This product has not been shown to relieve cold symptoms” was introduced in red

44 Id..
45 See Manoj Hastak, Effects of Exposure to Packages of Several Homeopathic Products on Consumer Takeaway
and Beliefs, Report Submitted to the Federal Trade Commission (August 2012), Ex. C.
46 Id. at 2.
47 Id.
48 Id.
lettering in a black box at the bottom of the back panel of the package.\textsuperscript{49} The three versions of
the Boiron product Oscillococcinum consisted of the original product available in the market at
the time, a version that was identical to the product available in the market except that a more
prominent “homeopathic” disclosure was added just above the brand name on the front panel,
and a third version that was identical to the original version on the market except that the
statement “This product has not been shown to relieve flu-like symptoms” in red lettering
replaced the contact information for the manufacturer at the bottom of the back panel of the
package.\textsuperscript{50}

The four versions of the Hylands Arnica product consisted of an original version of the
actual product available in the market at the time, except that any mention of the symptoms
ostensibly treated by the product and company contact information were removed from the back
panel, and a version that was identical to the original version except that the word
“HOMEOPATHIC” was made larger and more prominent on the front panel and the company
name was made smaller to make room for the larger “homeopathic” disclosure. A third version
was identical to the original version except that the statement “\textbf{Notice}: This product has not been
shown to relieve pain symptoms” in red lettering was added at the bottom of the back panel, and
a fourth version was identical to the original version except that the statement “\textbf{Notice}: The
ingredients in this product have not been tested for effectiveness” in red lettering was added at
the bottom of the back panel.\textsuperscript{51} After viewing a 3-D image of the product assigned to them,
respondents answered a short questionnaire comprising closed-ended questions.\textsuperscript{52}

\textsuperscript{49} Id. at 2-3.
\textsuperscript{50} Id. at 3.
\textsuperscript{51} Id. at 3-4. Screening questions were used to ensure that the respondents were in the target market for at least one
of the three products. Ex. B at 4. To participate in the survey, respondents had to have purchased for themselves or
for a family member one of the three product categories of interest (i.e., a product to relieve (a) cold symptoms for
children aged 2-12, (b) pain, or (c) flu-like symptoms) within the past 12 months. In addition, respondents were
The copy test results reveal that many consumers mistakenly believed that the FDA has approved homeopathic products for efficacy. After controlling for “yea saying,” the copy test showed that between 10% and 30% (10.3% to 28.6%) of respondents exposed to the original product packaging for the three products indicated that they believed that a government agency like the FDA had approved the products for efficacy. Although making the word “homeopathic” more prominent on the Similasan label significantly reduced the belief that the product was FDA approved, it did not have a similar effect for either the Oscillococcinum or Arnica products. Likewise, at least one of the two disclosures utilized in this study significantly reduced the misperception of FDA approval for each product. However, after controlling for “yea saying,” the copy test showed that 18.9% of respondents exposed to the Similasan product packaging still indicated that they believed that a government agency like the FDA had approved the product for efficacy, as did 7.4% to 8.0% of respondents exposed to the packaging of the other two tested products. It is possible that different or more prominent disclosures could further reduce the percentage of consumers with the misperception that homeopathic products are FDA approved. Whether other disclosures could effectively and

excluded if they were under 18 or if they or anyone in their household worked in marketing research, a grocery or a drug store, or for a drug or pharmaceutical company. Id.

52 Id.
53 Id. at 14.
54 “Yea saying” is the tendency to agree with questions asked regardless of content. As the survey report notes, affirmative responses to the FDA statement were adjusted by subtracting affirmative responses to a control statement designed to capture “yea saying.” The control question asked consumers if they believed that that American Medical Association certified that the product was more effective than other remedies in relieving the symptoms the product claimed to relieve. Control questions are used to control for measurement error, including yea-saying bias, inattention, and other noise factors that may result from the provision of a closed-ended question format. See J. Craig Andrews & Thomas J. Maronick, Advertising Research Issues from FTC versus Stouffer Foods Corporation, 14 J. PUB. POL. & MARKETING 305 (1995).
55 Id. at 9. Before controlling for “yea saying,” responses ranged from 30% to 56% (32.6% to 56.0%).
56 Id.
57 Id. at 9-10.
consistently eliminate such misperceptions is an open question; however, this research shows the persistence of mistaken consumer beliefs about government approval for homeopathic products.

The copy test results also showed that consumers mistakenly believed that the manufacturers of homeopathic products tested their products on people in order to show their effectiveness. After controlling for “yea saying,” the copy test results showed that about 20% to 30% (22.8% to 33.6%) of respondents exposed to the original product packaging for the three products indicated that they believed the manufacturers had tested the products on people to show their effectiveness. These results support the conclusion that consumers have incorrect perceptions about human efficacy testing for homeopathic products.

C. Additional Observations

In addition to what we found in our copy test and focus group research, the FTC staff has observed other potential causes of consumer confusion in the marketing of homeopathic remedies. We believe that consumer confusion likely is created by the retail store shelf placement of homeopathic products side-by-side with conventional medicine that, in fact, has been approved by the FDA and tested on humans for efficacy. Confusion is likely created, as well, by the terminology used in homeopathy product labeling. In current labeling for homeopathic products, a manufacturer normally states that a product contains a particular substance in an amount that is expressed as a number followed by an “X,” such as “2X.” For

---

58 Id. at 14.
59 Id. at 11; see supra note 13. Before controlling for “yea saying,” responses ranged from approximately 45% to 57%.
60 Few homeopathic remedies have been subjected to human clinical trials under controlled conditions, and the vast majority of those that have been have not shown positive results. See, e.g., Evidence on the effectiveness of homeopathy for treating health conditions, Australian Government National Health and Medical Research Council (NHMRC) (Mar. 2015), available at http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02a_information_paper.pdf (last visited June 2, 2015).
instance, 2X represents a dilution of 1 to 100 (1:100), or, in other words, a 1% concentration. For the average consumer or even a sophisticated one, it is difficult to understand what 2X means.

The FTC staff is concerned that consumers may choose homeopathic products over proven medicine based on any or all of the misperceptions and incomplete or incorrect information described above. As our research has indicated, once consumers were given access to basic information about homeopathy, they were more skeptical of the homeopathic treatment than when they incorrectly believed that homeopathic was simply a synonym for “natural” and had no knowledge of the principles behind homeopathy.

**D. FTC Staff’s Evaluation of Likely Consumer Confusion**

Overall, the FTC staff’s copy test and focus group research, combined with other research and market observations, suggest that consumers have an incomplete and incorrect understanding of what homeopathic products are and how they are regulated. Many consumers may incorrectly believe these products are pre-approved by the FDA and tested on humans for efficacy. To add to this confusion, homeopathic products are placed side-by-side in retail stores throughout the United States next to products that are actually pre-approved by the FDA and tested on humans for efficacy. Finally, homeopathic product labels are confusing and do not conform with conventional product labeling. A consumer’s choice to use homeopathic medicine based on the above factors could cause harm. The FTC staff believes that the FDA should take these factors into consideration in its review of the regulatory framework for homeopathic products.

**VI. CONCLUSION**

The FTC staff believes that FDA’s regulatory framework, which potentially conflicts with the Commission’s advertising substantiation policy requiring that health-related efficacy
claims be supported by competent and reliable scientific evidence, may be harmful to consumers. In addition, the available evidence suggests that consumers have incomplete and sometimes incorrect information about homeopathy and homeopathic medicines. Accordingly, the FTC staff recommends that the FDA reconsider its regulatory framework for homeopathic medicines to address the concerns discussed in these comments.
Basis of Inquiry: As part of its routine monitoring program, NAD requested substantiation for pharmacist recommended and performance claims made in a print advertising by Similasan Corporation USA for its Similasan Earache Relief Ear Drops. In the print advertisement, the product is shown beside a prominently featured claim, “#1 Ear Pain Reliever,” next to which is the following text in larger print: “Recommended by Pharmacists 6 Times more often for Ear Pain over Tylenol, Motrin, and Aleve.” The claims “Healthy Relief” and “Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics” also appear on the product packaging. The following claims are at issue:

“Recommended by Pharmacists six times more often for Ear Pain over Tylenol, Motrin, and Aleve combined.”

“Healthy Relief.”

“Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics.”

Advertiser’s Position:

I. “Recommended by Pharmacists six times more often for Ear Pain over Tylenol, Motrin, and Aleve combined.”

As support for this claim, the advertiser referred to a survey conducted by Pharmacy Times magazine of brands most recommended by pharmacists for earache relief which revealed that Similasan received 49.43 percent of the recommendations as compared to Tylenol, Motrin, and Aleve (receiving a combined 7.9 percent of the recommendations). During the pendency of the inquiry, the advertiser informed NAD that it would permanently discontinue the “Recommended by Pharmacists six times more often for Ear Pain over Tylenol, Motrin, and Aleve combined” claim because a review of the study’s methodology revealed that only two products were named for earache relief (though some write-ins listed other products).

II. “Healthy Relief”; “Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics.”

The advertiser asserted that the claim “Healthy Relief” is a tagline and a registered trademark for its line of homeopathic drug products and is referenced in the advertisement solely because it appears on the product packaging. However, the advertiser noted that its product packaging and advertising prominently disclose that the product is homeopathic in nature and maintained that homeopathic manufacturers are not required to prove the safety and efficacy of their products.
The advertiser explained that "Healthy Relief" is intended to convey to consumers that the company's homeopathic products are different than typical over-the-counter (OTC) drugs because they are intended to treat symptoms without the use of chemicals that can cause side effects and interactions with other drugs. The advertiser noted that the level of active ingredients in homeopathic products is approximately 10 percent and that the product is further diluted. The advertiser argued that its product is marketed and labeled in compliance with the U.S. Food and Drug Administration's (FDA) compliance policy guide, "Conditions Under Which Homeopathic Drugs May be Marketed" (CPG)\(^1\), in that it complies with both the requirements of the Homeopathic Pharmacopoeia of the United States (HPUS)\(^2\) and that the concentrations of each of its ingredients is far below the maximum level allowed by the HPUS for OTC products as the most concentrated ingredient is present at one part per trillion.

The advertiser also maintained that the term "Healthy Relief" was based on the results of a survey\(^6\) it conducted to determine consumers' takeaway of the term. Consumers who visited the Similasan Website were asked "What does Healthy Relief mean to you?," and of the 5,320 respondents, 70 percent associated the phrase "Healthy Relief" with the following attributes: no known side effects (16 percent), pain relief (16 percent), contains no harsh chemicals (14 percent), treats symptoms (13 percent), and safe to use (11 percent).

As to the claim, "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics" the advertiser argued that its product has not been shown to cause side effects or interact with other drugs and that there are no confirmed cases where homeopathic drugs were determined to be the cause of an illness or side effect. It noted that the FDA found that in the few reported cases of illness associated with the use of homeopathic remedies, the remedies were not likely to be the cause because the active ingredients were highly diluted. The advertiser averred that while no study has been conducted on a product which contained the exact formulation as the Similasan product, and that such is not in any case necessary, it referred to two clinical trials using products that contain the active ingredients in the Similasan product. Taken together, the advertiser argued that the claim that Similasan "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics" was substantiated.

Decision:

During the pendency of this inquiry, the advertiser informed NAD in writing that it had permanently discontinued the claim "Recommended by Pharmacists six times more often for Ear

---

\(^1\) FDA/ORA CPG 7132.15, Conditions Under Which Homeopathic Drugs May be Marketed. Adopted by the FDA in 1988, the CPG offers guidance to industry in the marketing of homeopathic drugs.

\(^2\) The HPUS defines the legal standards for strength, quality and purity for drug products in order for them to be officially labeled as homeopathic drug products and is referenced as the legal source of information on homeopathic drug products in the Federal Food Drug and Cosmetic Act (21 U.S.C. § 301). It is administered and updated by the Homeopathic Pharmacopoeia Convention of the United States.

\(^6\) The advertiser advised that consumers can access the Similasan website through a variety of search engines and that they are referred to the survey upon clicking on a link called "valuable coupon" which they need to complete before they can download the coupon. The advertiser noted that its website makes clear that the survey is optional.
As to the "Healthy Relief" claim, NAD determined that its placement on the product packaging (directly under the brand name and not in conjunction with the performance claims) is likely to be understood by consumers to be a designation for the advertiser's line of homeopathic products rather than a product performance claim requiring substantiation.

Concerning the claim that Similasan "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics," there are two distinct components: the efficacy claim (relieves pain, soothes and calms) and the safety claim (safe for use with antibiotics). As to the efficacy claim, NAD determined that the underlying issue is not whether the ingredients in the product meet the legal standards for strength, quality and purity for drug products as defined by the HPUS or the CPG but, rather, whether there is sufficient evidence that the product itself actually soothes, calms and relieves ear pain.

It is well-established that claims concerning the efficacy of health products should be supported by competent and reliable scientific evidence. In cases that involve express claims of product performance, an advertiser should affirmatively demonstrate that the advertised product actively performs the function or provides the benefit claimed in the advertisement. However, NAD recognizes that there may be instances when general product efficacy claims promising health benefits can be substantiated without clinical studies of the specific product in question (e.g., the efficacy of certain ingredients for the claimed benefit) where the advertiser demonstrates that it is scientifically sound to draw conclusions from reliable studies and data and apply them to the performance claimed by the advertised product.

As support for the "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics" claim, the advertiser submitted two clinical studies on ingredients in the advertiser's product as well as excerpts from homeopathic texts.

As to the clinical studies, neither used a treatment whose formulation is similar to that found in the Similasan product; rather, both used single ingredient treatments. The first study involved a six-week randomized, double-blind placebo controlled pilot study of 75 children aged 18 months to six years of age diagnosed with acute otitis media (AOM). The infants assigned to the

---

4 Matrixx Initiatives, Inc/Zicam L.C.C (Zicam Cold Remedy Nasal Gel), Report # 4286, NAD Case Reports (February 2005); Green Pharmaceuticals, Inc (SnoreStop), Report # 4013, NAD Case Reports (January 2003).
5 Playtex Products, Inc. (Baby Magic Bath Products and Baby Magic Shampoo), Report # 3680, NAD Case Reports (August 2000).
6 Council on Natural Health (Smoke Away System), Report # 4180, NAD Case Reports (May 2004) (where NAD determined that the advertiser of a homeopathic product provided reliable scientific evidence as to the ingredients in its product being helpful in assisting smokers in their attempts to quit smoking though it did not support the claims that it will make them smoke-free or eliminate cravings or withdrawal symptoms).
7 Acute otitis media is the presence of fluid, typically pus, in the middle ear with symptoms of pain, redness of the eardrum, and possible fever. In this study, 36 children received a homeopathic treatment and 39 were given a placebo. Of the 16 different homeopathic medicines that were available (and most commonly used to treat AOM),
homeopathic group received one of eight possible treatments including chamomilla and sulphur both of which are present in the Similasan product. Indeed, the authors of the study stated that the purpose of the study was to determine which homeopathic treatment(s) (which consisted of one ingredient) would be appropriate to treat AOM. At the outset, the authors noted that AOM in children heals spontaneously without therapy in most cases. The infants’ parents were asked to record a diary of symptoms which included pain, fever, irritability, appetite, energy and sleep and tympanograms (a test used to detect disorders of the middle ear) were taken of the subjects to determine the amount of middle ear effusion at the beginning of the study and at weeks two and six. The authors concluded that there was a decreased symptom score at all points during in the study for the group receiving homeopathic medicine as compared to placebo, with a significant decrease in symptoms at 24 and 64 hours after treatment, and no reported side effects, which it deemed noteworthy though it noted that a larger study would be needed to verify the results. They also referred to a metaanalysis of 89 homeopathic trials which found, at a 95 percent confidence level, insufficient evidence that homeopathy is clearly efficacious for any single clinical condition.

The second study was an open nonrandomized non-blinded, observational study of 131 children, with 103 children receiving one of 12 possible homeopathic treatments (consisting of one ingredient) and 28 receiving a conventional treatment (nasal drops, antibiotics, secretolytics and/or antipyretics). The main outcome measures were duration of pain, duration of fever and the number of recurrences after one year. As in the first study, the children in the homeopathic group were assessed individually by a qualified homeopathic practitioner and prescribed the most appropriate remedy according to their specific presentation of symptoms. The study concluded that homeopathy may provide a good alternative to conventional treatment in that reduced symptoms were reported in the homeopathic group compared with those in the conventional treatment group (including decreased duration of pain and fewer recurrences after one year), with no serious side effects reported from either group (with only slight side effects in the conventional treatment group). The authors acknowledged, however, that the study was unreliable because it was not randomized or double-blind.

While the studies’ authors noted the importance of individualization of homeopathic treatment, whereby patients with the same medical diagnosis might receive different medicines based on specific symptoms of illness in each patient, NAD is not charged with determining which course of treatment is preferable but instead looks to the claim at issue to determine if the scientific evidence constitutes reliable support. Serious methodological flaws and the preliminary nature of the findings on the efficacy of homeopathy in treating AOM undermine the reliability of both studies. Importantly, both of these studies were designed to measure the effectiveness of a homeopathic treatment (consisting of only one ingredient) compared with conventional medicine or placebo and not a combination of ingredients as present in the advertiser’s product. In eight were prescribed by the homeopathic practitioners. The most common medicines prescribed in 88 percent of the cases were Pulsatilla nigricans (62.7 percent), Chamomilla (10.7 percent), Sulphur (9.3 percent) and Calcaria carbonica (5.3 percent). Each child was seen by homeopathic practitioners (two medical doctors and a physician’s assistant) and a naturopathic physician. Follow-up visits were made by an otolaryngology resident.
addition, it is unclear which of the homeopathic ingredients (particularly Chamomilla, Mercurius solubilis and Sulphur found in the Similasan product) was deemed effective in helping to relieve AOM symptoms to even afford the possibility of an ingredient claim. Further, the dilutions of the ingredients in the studies differ from those in the advertiser's product. As such, the studies are insufficiently reliable to afford extrapolation of their findings to support the efficacy portion of the challenged claim ("Relieves Pain, Soothes & Calms").

NAD also reviewed excerpts from homeopathic literature on the ingredients in Similasan and determined that while these sources may support the legal standards for strength, quality and purity for drug products as prescribed by HPUS or the CPG and reveal the potential efficacy of the individual ingredients in relieving symptoms associated with AOM, there is no evidence in the record which demonstrates that the efficacy of individual ingredients will not be diminished in any way with the addition of other ingredients, since Similasan contains a combination of ingredients, particularly given that they are even more diluted than required by the HPUS.

As to the “Safe to Use With Antibiotics” portion of the claim, NAD determined that the fact that the ingredients in the product are highly diluted cannot in and of itself provide sufficient support for a claim that the product is safe to use with antibiotics. As NAD has noted in past decisions, it is very important that claims relating to the safety of health-related products be supported by competent and reliable scientific evidence. This is particularly important with respect to homeopathic drugs, since marketers of homeopathic drugs are not required to prove their safety before they are sold to the public, and is supported by the CPG which specifically provides that a product’s compliance with requirements of the HPUS does not establish that it has been shown “by appropriate means to be safe, effective and not misbranded for its intended use.”

For all the foregoing reasons, NAD recommended that the claim “Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics” be discontinued.

Conclusion:

NAD appreciated that the advertiser voluntarily discontinued its claim, “Recommended by Pharmacists six times more often for Ear Pain over Tylenol, Motrin, and Aleve combined,” an action it deemed to be necessary and proper given the evidence in the record. NAD determined that the advertiser’s evidence was not sufficiently reliable to support the claim “Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics” and, accordingly, recommended its discontinuance.

See, e.g., Avon Products, Inc. ("ELLI-U-SCLL-P": Anti-Cellulite Slimming Treatment), Report # 4124, NAD Case Reports (December 2003).

John Henry Clarke, M.D., A DICTIONARY OF PRACTICAL MATERIA MEDICA (Health Science Press); Douglas M. Gibson, STUDIES OF HOMEOPATHIC REMEDIES (Beaconsfield Publishers Ltd.).

Playtex Products, Inc. (Baby Magic Bath Product and Baby Magic Shampoo), Report # 3680, NAD Case Reports (August 2000).


Supra note 1.
Similasan Corporation USA welcomes the opportunity to participate in this process and appreciates the important role that the NAD plays in industry’s self-regulatory scheme. In this case, however, Similasan regretfully concludes that the NAD has reached an incorrect result as to the core claims it has challenged. Similasan appreciates that the NAD agrees with its position that “Healthy Relief” is not a performance claim but rather a designation for Similasan’s line of homeopathic products. The performance “claims” which are the subject of this inquiry appear on a photo of Similasan’s Earache Relief Drops package in a free standing circular. The claims appear on the principal display panel of the package and on the Drug Facts panel. Similasan believes, and the NAD does not dispute, that this product is labeled and marketed in accordance with the Food and Drug Administration’s Compliance Policy Guide (CPG) on the sale of homeopathic drugs, a special category of drugs specifically recognized in the Federal Food, Drug, and Cosmetic Act since its passage in 1938. Yet the NAD believes that showing a photo of a legally marketed product is indefensible because the product does not have “scientific” evidence to support those claims in the manner that the NAD believes is required. Similasan does not agree that legally appropriate claims on a product package are somehow inappropriate when they appear in advertising.

Homeopathy is an alternative school of medicine which has existed for more than 200 years. It does not rely upon nor especially embrace the value of clinical trials to demonstrate efficacy. As a result, very few homeopathic drugs have undergone clinical testing. FDA fully understood that this was the case when it issued its Compliance Policy Guide in 1988 concerning the marketing of homeopathic drugs. The NAD appears to be imposing a standard of proof which is imposed neither by the FDA nor the Federal Trade Commission. Under the NAD’s view, virtually no homeopathic drug could be advertised to the public. That is surely an incorrect result.

It is the homeopathic literature (the materia medica), not clinical trials, which are the foundation for claims of homeopathic efficacy, and these references are recognized as such by FDA’s Compliance Policy Guide. The NAD’s assertion that a homeopathic product must prove that “the efficacy of individual ingredients [in a combination product] will not be diminished in any way with the addition of other ingredients” is misplaced. Neither the HPUS nor the FDA require such “proof.” Similasan does not accept the NAD’s view that a legally marketed homeopathic drug may not be advertised to the public.

Nonetheless, because of its respect for the NAD and the self-regulatory process, Similasan will take the NAD’s recommendations into account when developing future advertising and will not use again the advertisement in question. (#4650 AMU/AT, closed 04/02/2007)
EXHIBIT B

Part 1
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STUDY OVERVIEW</strong></td>
<td></td>
</tr>
<tr>
<td>Background and Objectives</td>
<td>1</td>
</tr>
<tr>
<td>Methodology</td>
<td>2</td>
</tr>
<tr>
<td>Limitations</td>
<td>3</td>
</tr>
<tr>
<td><strong>KEY FINDINGS</strong></td>
<td>4</td>
</tr>
<tr>
<td>Identify Non-Prescription Products Commonly Used to Treat Cold Symptoms</td>
<td>5</td>
</tr>
<tr>
<td>Obtain Reactions to Sample Non-Prescription Products</td>
<td>6</td>
</tr>
<tr>
<td>Explore Perceived Differences by Product Category</td>
<td>7</td>
</tr>
<tr>
<td>Determine Awareness and Perceptions of Homeopathic Products</td>
<td>11</td>
</tr>
<tr>
<td><strong>IMPLICATIONS</strong></td>
<td>16</td>
</tr>
<tr>
<td><strong>APPENDIX A: Respondent Profile</strong></td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>A-1</td>
</tr>
</tbody>
</table>

A-1
Study Overview
The Federal Trade Commission (FTC) is exploring consumer understanding of various non-prescription products including conventional, herbal and homeopathic products. Market research was conducted to explore the understanding and knowledge of non-prescription products among two key consumer segments: General Adults and Parents.

The overall objective of the research is to understand the extent to which consumers may be confused about the differences between conventional, herbal and homeopathic non-prescription products. Specific objectives include the following:

- Identify non-prescription products commonly used to treat cold symptoms
- Obtain reactions to sample non-prescription products
- Explore perceived differences by product category (including evidentiary support and regulatory oversight)
- Determine awareness and perceptions of homeopathic products
Qualitative research in the form of focus groups was the recommended methodology because they allow for an in-depth exploration of consumer behaviors and perceptions as well as reactions to stimuli.

A total of two focus groups were conducted in Baltimore, Maryland on December 8, 2010.
- One focus group was conducted with General Adults
- One focus group was conducted among Parents

Shugoll Research, with input from the FTC, developed two screening questionnaires to recruit focus group respondents. The principal criteria for participation in the General Adult group were:
- Purchased at least one non-prescription product to treat cold symptoms in the past year
- Is the sole decision maker or shares in the responsibility for deciding which non-prescription products to buy to treat cold symptom
- A mix of non-prescription category users including conventional, herbal and homeopathic products
- A mix of ages between 30 and 69
- A mix of demographic characteristics including education, employment, household income and ethnicity
Methodology

- The principal criteria for participation in the Parent focus group were:
  - Must have a child between the ages of 4 and 10.
  - Purchased at least one non-prescription products to treat cold symptoms for their children between the ages of 4 and 10 in the past year
  - Is the sole decision maker or share in the responsibility for deciding which non-prescription products to buy to treat cold symptoms for their children
  - A mix of ages, predominantly ages 25 to 54
  - A mix of demographic characteristics including education, employment, household income and ethnicity
- A total of 16 consumers (8 General Adults and 8 Parents) participated in the research. A summary of the respondent profile may be found in Appendix A.
A qualitative research methodology seeks to develop directions rather than quantitatively precise or absolute measures. The limited number of respondents involved in this type of research means the study should be regarded as exploratory in nature, and the results used to generate hypotheses for decision making and further testing. The non-statistical nature of qualitative research means the results cannot be generalized to the population under study with a known level of statistical precision.
Key Findings
Identify Non-Prescription Products Commonly Used to Treat Cold Symptoms
Awareness of non-prescription cold products is very high.

- General Adults and Parents readily list a dozen or more non-prescription cold products. Frequently cited products on an unaided basis include:
  - Zicam
  - Aspirin
  - Tylenol
  - Motrin
  - Robitussin
  - Vick's Vapor Rub
  - Sudafed
  - Airborne
  - Vitamin C
  - Echinacea
  - Orange Juice
  - Dimetapp

Most keep several products on hand, primarily conventional products.

- General Adults tend to keep products designed to treat cold symptoms.
  
  "Sudafed." (General Adult)

  "Cough syrup." (General Adult)

  "Airborne if it's just starting." (General Adult)

  "I have Nyquil, Vitamin C, cough syrup." (General Adult)
Non-Prescription Products Commonly Used to Treat Cold Symptoms

- Parents are likely to have fever reducing products in their medicine cabinets in addition to those designed to treat cold symptoms.

  "I have every one of them. I swear to you." (Parent)

  "You’ll definitely find the fever reducers, but not so much the cough [products]." (Parent)

  "Triaminic, Robitussin." (Parent)

  "Dimetapp PM and Robitussin." (Parent)

  "I have Children’s Tylenol and Children’s Advil and a lot of Vick’s and I do have these strips." (Parent)

- Several Parents note that they are frequently shopping for a product to treat cold symptoms in response to a sick child.

  General Adults and Parents are likely to group or categorize products in a number of ways including conventional versus “natural” products.

  - General Adults cited the following ways to categorize or group products:

    - Stage of the cold: onset vs. full blown
    - Time of day: daytime vs. nighttime
    - Natural or homeopathic vs. chemical based drugs
    - Age: children vs. adults
    - Symptoms: single vs. multiple
    - Strength: aggressive vs. more lax
When asked to identify products that belong in the "natural" group, General Adults listed herbs and vitamins, orange juice, lemon, hot tea and Echinacea. Noticeably absent from this group was Airborne. Aspirin, Tylenol, Robitussin, and Zicam were categorized as conventional products.

Parents did not categorize the products by conventional vs. non-conventional. Rather, they grouped the children cold products in the following ways:

- Stage of the cold: prevention vs. onset vs. full blown
- Time of day: daytime vs. nighttime
- Age: age of the child
- Symptoms: fever vs. cough vs. runny nose
- Familiarity: trusted brand/product vs. unknown

There are few products consumers avoid and none are explicitly avoiding herbal or homeopathic products.

General Adults and Parents are inclined to avoid certain conventional non-prescription products based on past experience and/or hearsay.

"I won't use Zicam. I heard bad things about that on TV and on the Internet." (General Adult)

"I won't use Mucinex. It didn't work." (General Adult)

"I don't really like Robitussin. I had a bad experience with it." (Parent)

Some Parents expressed concern for products that cause drowsiness or ones that are perceived as "too strong."

"I wouldn't use Mucinex [for my child], even though I have it for myself. My kids are too young for that because it's strong, very strong." (Parent)
Obtain Reactions to Sample Non-Prescription Products
Consumers reject the herbal Kold Kare and homeopathic Cold Care.

- General Adults were exposed to three non-prescription product samples designed to treat cold symptoms. They immediately reject the herbal and homeopathic products primarily due to the product names and packaging. General Adults are skeptical toward products that feature misspelled words.

  "It’s not even spelled right. K-o-l-d. It looks like something that they’re giving away. ‘Here, try this.’" (General Adult)

  "A generic brand." (General Adult)

- Many adults are in the habit of searching for and reading active ingredients on non-prescription cold products.

  "The number one thing that stood out for me is I didn’t see a list of active ingredients."
  (General Adult)

  "[With Tylenol] I know what I’m putting in my body. It’s a chemical reaction and an understood situation. But I know how much I’m putting in. Whereas with this one [Kold Kare], it doesn’t tell you.” (General Adult)

- One consumer questioned the ingredients in the herbal product.

  "I would feel differently if I was more aware of what the stuff is or what it does. If I knew what leaf extract was or the benefits, then I wouldn’t be as leery.” (General Adult)
Several adults dislike the Cold Care Kit packaging.

- Specifically, some adults are unclear how the product is supposed to be administered.

  "It looks like something that you’d probably get by injection. Reading the package doesn’t tell me how to take it." (General Adult)

  "It does look like it’s little vials of something." (General Adult)

Consumers group the three products into two categories: Known versus Unknown.

<table>
<thead>
<tr>
<th>Known</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tylenol Cold</td>
<td>Kold Kare</td>
</tr>
<tr>
<td>Cold Care Kit Boiron</td>
<td></td>
</tr>
</tbody>
</table>

"Well, it’s known versus unknown. I’d group them by saying Kold Kare and the Care Kit against the Tylenol." (General Adult)

"It [homeopathic] means not chemical." (General Adult)

"Better effectiveness [Tylenol] versus questionable effectiveness [Kold Care and Care Kit]." (General Adult)

"Homeopathic versus traditional." (General Adult)
Parents, particularly mothers, immediately focus on the visuals and the text on the front of the packages.

- Parents were exposed to four sample products. Most immediately focused on the information on the front of each product package. On the Similasan product, for example, parents immediately commented on the elephant visual and the stated age range for kids. On the Hyland’s Cold ‘n Cough product, they noted the “Sugar Free” claim and on the Sudafed PE product, they commented on the “non-drowsy” claim.

“This Hyland’s Homeopathic. I noticed the safe age was right on front, so you don’t have to look for it. And it was sugar free; I like that. And 100% natural.” (Parent)

“That actually caught my eye [Sugar Free].” (Parent)

“I would buy it [Similasan] for that elephant.” (Parent)

“The Similasan has the age right on the front. It’s easily found, right on the front, not like on the Triaminic and the Sudafed, where you actually have to read the dosing to find if your child is old enough to take it or not.” (Parent)
Parents grouped the four products into two categories: Familiar versus Homeopathic

Familiar
- Tylenol Cold
- Triaminic Day Time Cold & Cough

Homeopathic
- Hyland’s Cold ‘n Cough
- Similasan Cold & Mucus Relief

Parents immediately identified two categories for the four sample products.

“Two homeopathic versus big name pharmaceuticals.” (Parent)

“You have the two homeopathic products, and then the two that you hear commercials on a million times a day.” (Parent)

A few parents clearly state that they prefer the familiar products.

“I still favor these two [Triaminic and Sudafed] over these two [Cold ‘n Cough and Cold & Mucus Relief], all the time. I personally believe brand names work better than the generics.” (Parent)

“I know if I give my child Tylenol as a fever reducer, it will reduce the fever.” (Parent)
Explore Perceived Differences by Product Category
General Adults and Parents clearly differentiate conventional non-prescription products from non-conventional products.

- Consumers do not have difficulty defining or categorizing conventional non-prescription products.

- However, most struggle when asked to distinguish between herbal and homeopathic products.

  Most consumers associate homeopathic products with natural or non-chemical products.

  "I would equate it [homeopathic] to organic. Something that occurs in nature." (General Adult)

  "I think it's more natural, pure, without chemicals. Without looking up the definitions, that's what I would think." (General Adult)

  "Natural, not chemically enhanced." (General Adult)

  "Natural, not synthetic." (Parent)

  "Home remedy. Something that my grandmother would concoct." (General Adult)

  "Something you won’t have to buy. Like soup or something." (Parent)

- A few are a bit more familiar with the concept behind homeopathy.

  "It’s kind of like a natural kind of vaccine. For instance, if someone has allergies, rather than take medicine they give you allergy shots which essentially stimulates the body’s response to those allergies." (Parent)
Once definitions for conventional, herbal and homeopathic are provided, consumers generally have no difficulty assigning products to a particular category.

- General Adults and Parents easily categorized brand name pharmaceuticals as conventional products. The following products are perceived as conventional:
  - Tylenol
  - Zicam
  - Robitussin
  - Motrin
  - Sudafed
  - Dimetapp

- Similarly, they categorized Vitamin C, orange juice and certain throat lozenges as herbal products.
  - Echinacea
  - Hot tea with lemon

- However, a few express some confusion toward homeopathic products.

  "I'm just curious whether there's not sort of a distinction between homeopathic and herbal [products]. The things on the back of the homeopathic packages look like they could be plant names, but I don't know what they are. If they're not herbal and they're not drugs, then exactly what is that stuff that I don't recognize?" (Parent)

  "I thought of homeopathic as being herbal supplements." (Parent)

- There is some confusion regarding Airborne. Some consider it a herbal product, while others are unsure.
It should be noted that consumers do not readily differentiate between evidentiary requirements and federal regulations.

- General Adults and Parents tend to refer to, and discuss, evidentiary requirements and federal regulatory oversight interchangeably.

Consumers expect the manufacturers of conventional non-prescription products are required to meet more stringent evidentiary requirements than herbal and/or homeopathic products.

- It is generally believed that manufacturers of conventional non-prescription products must be able to support their claims with scientific evidence.

- However, consumers have varying opinions regarding the evidentiary requirements for herbal and homeopathic products. Some consumers indicate there are no requirements; others insist there must be some governmental oversight of these products, and still others are unsure, but hopeful, that there are some requirements.

"Conventional probably has a higher standard. I don’t know what the exact standards are, but I would say there is some testing.” (General Adult)

"I don’t think so. I think they [herbal products] can make the claims, but they don’t have to be substantiated. We know that this plant or root has been known to do x, y, z, but they’re not telling you to take it and it will fix x, y, z. It has been known to do that.” (General Adult)

"I would think that anybody that is putting something out there would have to have to some type of study. I would think if there’s a bad reaction, they wouldn’t want to be sued...so they have to do some kind of studies. Now, whether it’s long term like your conventional [products], I don’t know. But I would think homeopathic and herbal do studies. Maybe not as extensive, but they have to do some type of studies and they go by the majority of their studies.” (General Adult)

"I’m afraid there is none [evidentiary requirements] that they have to have. I would hope that the FDA is looking out for us as consumers.” (Parent)
Evidentiary Requirements and Federal Oversight

“I agree. We’re relying on the FDA or whoever to test these products and saying, ‘Yes, what’s on the box is really what’s in there and nothing else.’” (Parent)

“You can use imagery that suggests it’s medicine, but you could have it classified wholly differently.” (Parent)

Similarly, most consumers perceive that federal agencies such as the Food & Drug Administration (FDA) actively review the evidence supplied by manufacturers of conventional non-prescription products. Again, they are divided on the role of the federal government with regard to herbal and homeopathic products.

- Consumers expect the government to hold conventional products to higher standards.
  
  “I think you need a lot for conventional [products], because you’ve got a lot of chemicals and things in there. You have to pass FDA testing and everything. It can take a lot of years.” (General Adult)

  “I think the FDA requires Tylenol, for example, to research how long it really takes to get rid of whatever your problem is. Because you’ll notice on the back of Tylenol it says, ‘Take this for no longer than four days, or consult your physician.’” (General Adult)

  “I think it’s done by ingredient. The ones that have the drug, the chemical compounds, are going to be more stringent. They’re going to be tighter on them. The ones that are using more natural products and stuff, I think the FDA wouldn’t check as closely.” (Parent)

- Some consumers believe herbal and homeopathic products face the same requirements as conventional products. Others disagree, or are unsure.

  “I don’t think it’s [homeopathic products] regulated as stringently as the conventional drugs. They’re not allowed to call it a drug.” (General Adult)
"I think they [FDA] are involved only if there is a specific claim: 'Use temporarily relieves nasal congestion due to the common cold, hay fever, or other respiratory allergies.' So then, I would assume they [manufacturers] had to submit some data that suggest that a control group that used a placebo had this result and the group that used the product had a better outcome, generally." (Parent)

"I would say their involvement is minimal to none." (General Adult)

"I don't think the FDA would waste their time with it [homeopathic products]." (General Adult)

"I think if they can bring it to the shelf of a drug store, it has to be reviewed by someone on the federal level." (Parent)

"I think they are [federal review of all products]. They better be because when you're giving it to a child, and if you kill somebody...you know?" (Parent)

"I can hope. That's all I can say, is that I would hope that someone took the time to say we have to look at herbal, at homeopathic [products]." (Parent)

"I think it comes down to what claims they make. It all has to do with the language. Because ultimately that's all that you can hold any company to." (Parent)

- Consumers value the involvement of the federal government.
  - Federal agency involvement and oversight provide a feeling of safety and trust.

  "When you have something that has FDA approval, they back it and they're saying that the chemicals in this substance are okay. It won't harm the body, it will help you." (General Adult)

  "To see how safe it is. To see whether you can use it when you shouldn't use it." (General Adult)

  "You're trusting that the FDA is looking out for everybody. So we trust them and hopefully, they are looking out for us." (General Adult)
Determine Awareness and Perceptions of Homeopathic Products
Although consumers are generally aware of homeopathic products, they exhibit very little understanding and knowledge of the underlying principles.

- Most consumers equate homeopathic products with natural and/or “home remedies.”
  
  “Homeopathic. I think it’s more natural, pure, without chemicals. Without looking up the definition, that’s what I would think.” (Parent)

- Even those who have purchased homeopathic products are unfamiliar with the Law of Similars and Law of Infinitesimals.
  
  “It’s not at all what I thought of as homeopathic. It’s just taken me a step back to where I’m now cautious.” (Parent)

  “Admittedly, I have a different idea of what homeopathic is than what you described. So now, I’m less sure.” (Parent)

  “I’m very, very familiar with that concept [homeopathy], and I never thought of it the way you described the definition or the two laws. It’s a very strange to me, this definition...so it’s taken me aback.” (General Adult)

Consumers find the two underlying principals of homeopathy – law of similars and law of infinitesimals – confusing.

- The underlying concept of the Law of Infinitesimals is particularly confusing and counterintuitive for many consumers.
  
  “It’s a little contradictory.” (Parent)

  “That [12X] means nothing to me. Nothing!” (Parent)

  “Are you sure that’s right? That doesn’t make any sense.” (Parent)
"Say if you make tea, and you put more water in it, it's not as flavorful. So, I'm thinking the more you dilute something, the more effective it is? That doesn't make sense!" (Parent)

- Parents, in particular, are motivated by the relatively few side effects of homeopathic products.
  - The relatively few side effects is comforting for some parents.
    "I don't cringe if one of the kids get into something that's homeopathic. If they grab the bottle of Tylenol or drugs, I know there is going to be an adverse reaction. Whereas, if you chewed up a bunch of herbs, you might not feel so hot, but I don't worry about them having a seizure or cardiac arrest or something drastic." (General Adult)
    "Well, who wouldn't [want to] take a product with no side effects?" (Parent)
  - The diminished risk of side effects made some a few consumers question the effectiveness of homeopathic products.
    "I like the fact that there are very few side effects. But one that's totally diluted, how aggressive is it going to be when you really need something? How long are you going to have to take something before you're cured of your cold or something else if is so totally diluted versus something that will be more aggressive? So, I kind of wonder about that, but I like the idea of no side effects." (General Adult)
    "If it's so diluted, then okay there are less side effects. But is my kid still getting healthy? Or is it going to take twice as long, or 100 times, or 12 times as long and 12 times the amount for them to get better? I don't want to give them something diluted just because there is less side effects if it's going to take them six weeks to get over a two-week cold. I want him healthy now!" (Parent)
Most consumers are reluctant to use homeopathic products.

- Most General Adults and Parents indicate they are likely to continue to use the conventional non-prescription products with which they are familiar.

  "I’m still going conventional because I know it has drugs in there and I want something that works fast.”
  (General Adult)

  “I want what has proven to work for me.” (General Adult)

  “I think if you’re going into the store with your child sick at home, you’re going to grab proven versus something [unknown].” (Parent)

  “When you give two teaspoons of that Motrin, it breaks the fever within the hour. And that’s what I’m looking at. The next time I’m buying my product, I’m looking at what have I used in the past? What works? What can I pick up? What is readily available? If my kid is sick, that’s what I’m going to look at. I’m not looking at green and stuff [Similasan product]. I’m looking at works. Period.” (Parent)

  “I am less interested [in homeopathic products] than I was before.” (Parent)

  “If you’re running to the store because your child is sick that day, then you’re probably going to get the tried and true.” (Parent)

- They are unlikely to purchase homeopathic products without the express recommendation from a trusted source (e.g., medical professional, family member, friend, etc.).

  “I’m going to me more skeptical. I’m going to ask a trusted source, ‘Have you tried this? Did this work for you?’” (General Adult)

  “Someone would have to tell me, ‘Hey, try this. It works.”’ (General Adult)
"This [Triaminic and Sudafed] is what the doctor tells or suggests for you to use and the ones you have had a history with. I'm with you. I'm not going to try these two [Cold 'n Cough and Cold & Mucus Relief]. But, if my doctor said, 'You know what? I've been suggesting to my patients to try this, it's really good. You might want to take a look at it,' then I would try it." (Parent)

Others, however, are more interested in homeopathic products because they are perceived as less harsh or because the manufacturing process it appears more scientific than they originally perceived.

"I would say herbal first, then homeopathic. And then if I really can't handle it, I'd go with the conventional." (General Adult)

"I go with the herbal, the vitamin C, huge quantities of vitamin C. And, in a day or so if I'm getting worse, it's conventional." (General Adult)

"When you think of homeopathic, you think of something from the 60's, concocting things. But here, it's more modern thinking, more scientific." (General Adult)

"Understanding what infinitesimal means, it actually makes me more open to homeopathic stuff. Basically, it's your flu shot, your anti-venom, things like that, that people could live or die from, are homeopathic according to the definition that you've given." (General Adult)
Implications
The following implications are based on study findings and the interpretation of those findings by the moderator/analyst. These implications may or may not represent the views of Federal Trade Commission representatives. The following implications are offered for consideration by the Federal Trade Commission:

- **Consumers have a high degree of familiarity and understanding of conventional non-prescription products.**
  - General Adults and Parents readily identify and classify conventional non-prescription products. They understand manufacturers of conventional products must be able to support their product claims and that the federal government oversees their compliance with these requirements.
  - Further, most are aware of how to read and interpret the product label by searching for the active ingredient.

- **Despite some claimed awareness of homeopathic products, consumers' knowledge and understanding of the underlying homeopathic principles is very low.**
  - Some consumers are aware of the term "homeopathic." However, most consumers are unable to articulate a category definition. Many consumers tend to group all non-conventional products together including homeopathic products into a single category, and use the terms "natural", "herbal" and "homeopathic" interchangeably.
  - Consumer response to the two underlying homeopathy principles is generally confusion. Most appear to grasp the Law of Similars at least at some level, but no one understood the Law of Infinitesimals. In fact, many question the efficacy of homeopathic products upon learning about the Law of Infinitesimals.
  - Even those consumers who self-reported that they have used homeopathic products were unfamiliar with the two underlying principles of homeopathy. They choose to use homeopathic products because they perceive they are more natural and less harsh on their body.
  - Overall, consumers were less interested and/or more guarded toward homeopathic products following the discussion of the two underlying principles of homeopathy. Several comment they would only choose a homeopathic product if it was recommended to them by a trusted source, while others remained attracted to the concept of homeopathy because of the perceived lower risk of side effects.
Visual images, product claims and packaging drive consumers' initial impressions of new products.

- No one was familiar with any of the sample products provided. Initially, General Adults and Parents focused on the front of the sample homeopathic products including the visual images, the product claims and the overall packaging itself.

- The incorrect spelling on the adult sample products was rejected by consumers and led some to conclude the products were “generic” brands.

- Parents, in particular, were attracted to the soothing visual images and the age specific information on the sample child products.
Appendix A: Respondent Profile
### Respondent Profile

<table>
<thead>
<tr>
<th>Non-Prescription Products purchased*</th>
<th>Total N=16</th>
<th>General Adults N=8</th>
<th>Parents N=8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over-the-counter</td>
<td>16</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Herbal</td>
<td>6</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Homeopathic</td>
<td>6</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Employment Status</th>
<th>Total N=16</th>
<th>General Adults N=8</th>
<th>Parents N=8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full-time</td>
<td>10</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Part-time</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Not working</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Retired</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education Level</th>
<th>Total N=16</th>
<th>General Adults N=8</th>
<th>Parents N=8</th>
</tr>
</thead>
<tbody>
<tr>
<td>High school graduate</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Some college</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>College graduate</td>
<td>9</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Post graduate</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Q.5GA: Which of the following types of non-prescription products have you purchased or used to treat any conditions?
Q.8A: Which of the following types of non-prescription products have you purchased or used for your child/children that are 4-10 years old to treat any conditions?
Q.8GA/10A: Are you currently?
Q.9GA/11A: Which of the following categories includes the highest level of education you have completed?

*Totals add up to more than sample size because respondents could choose more than one choice.
### Household Income

<table>
<thead>
<tr>
<th>Income Range</th>
<th>Total N=16</th>
<th>General Adults N=8</th>
<th>Parents N=8</th>
</tr>
</thead>
<tbody>
<tr>
<td>$30,000-$49,999</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>$50,000-$74,999</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>$75,000-$99,999</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>$100,000 or more</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

### Race and Ethnicity

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Total N=16</th>
<th>General Adults N=8</th>
<th>Parents N=8</th>
</tr>
</thead>
<tbody>
<tr>
<td>White/Caucasian</td>
<td>10</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>African American/Black</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Hispanic/Latin</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

### Gender

<table>
<thead>
<tr>
<th>Gender</th>
<th>Total N=16</th>
<th>General Adults N=8</th>
<th>Parents N=8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Female</td>
<td>11</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

Q.10GA/12A: Is your annual household income before taxes:
Q.11GA/113A: And to ensure we have a balanced sample, do you consider yourself to be:
Q.13GA/15A: Record gender
### Respondent Profile

#### Age for General Adults

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Total</th>
<th>General Adults</th>
<th>Parents</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-39</td>
<td>2</td>
<td>2</td>
<td>NA</td>
</tr>
<tr>
<td>40-49</td>
<td>3</td>
<td>3</td>
<td>NA</td>
</tr>
<tr>
<td>50-59</td>
<td>1</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>60-69</td>
<td>2</td>
<td>2</td>
<td>NA</td>
</tr>
</tbody>
</table>

#### Age for Parents

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Total</th>
<th>General Adults</th>
<th>Parents</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 or younger</td>
<td>0</td>
<td>NA</td>
<td>0</td>
</tr>
<tr>
<td>26-34</td>
<td>1</td>
<td>NA</td>
<td>1</td>
</tr>
<tr>
<td>35-44</td>
<td>6</td>
<td>NA</td>
<td>6</td>
</tr>
<tr>
<td>45-54</td>
<td>1</td>
<td>NA</td>
<td>1</td>
</tr>
<tr>
<td>55 or older</td>
<td>0</td>
<td>NA</td>
<td>0</td>
</tr>
</tbody>
</table>

#### Age of Children at Home*

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Total</th>
<th>General Adults</th>
<th>Parents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 4 years old</td>
<td>0</td>
<td>NA</td>
<td>0</td>
</tr>
<tr>
<td>4-10</td>
<td>8</td>
<td>NA</td>
<td>8</td>
</tr>
<tr>
<td>11-17</td>
<td>1</td>
<td>NA</td>
<td>1</td>
</tr>
</tbody>
</table>

---

Q.7GA: Which of the following categories includes your age?
Q.9P: Which of the following categories includes your age?
Q.3P: Do you have any children in the following age groups?
* Totals add up to more than sample size because respondents could choose more than one choice
EXHIBIT C
Effects of Exposure to Packages of Several Homeopathic Products on Consumer Take-Away and Beliefs

Report submitted to Federal Trade Commission

Manoj Hastak, Ph.D.¹

August 2012

¹ Manoj Hastak is Professor of Marketing in the Kogod School of Business at American University. He served as a consultant to the FTC on this project.
Effects of Exposure to Packages of Several Homeopathic Products on Consumer Take-Away and Beliefs

Introduction

A research study was designed to investigate consumer take-away (i.e., ad communication) and beliefs/opinions upon exposure to a package of one of three homeopathic drug products. The three products were: (a) Similasan: claimed to relieve cold-related symptoms in children aged 2-12, (b) Oscillococcinum: claimed to relieve flu symptoms, and (c) Arnica: claimed to relieve pain. The study was designed to address the following questions:

Communication

(1) Does the product package communicate to a significant number of people that it is a homeopathic product?
(2) Does increasing the prominence of the disclosure on the package that the product is homeopathic improve communication to people that it is a homeopathic product?

Beliefs/Opinions

(3) After viewing the packaging of these homeopathic drug products, do a significant number of people believe that a government agency like the Food and Drug Administration has approved the products as being effective in relieving symptoms associated with the common cold/flu/pain?
(4) After viewing the packaging of these homeopathic drug products, do a significant number of people believe that the manufacturer has tested the product on people to show that it is effective in relieving symptoms associated with the common cold/flu/pain?
(5) Are the beliefs identified in (4) weakened by the inclusion of a disclosure indicating that the product has not been shown to relieve cold/flu/pain symptoms?
(6) Are the beliefs identified in (4) weakened by the inclusion of a disclosure indicating that
the ingredients in the product have not been tested for effectiveness?

The data were collected for the FTC by Decision Analyst. Detailed tabulations of responses to all questions are available in the materials submitted by Decision Analyst to the FTC.

Method

The study was conducted online via Decision Analyst's online panel. Details of the panel are included in Appendix A. Respondents were invited to complete the screening questionnaire, and were offered an incentive of $3 if they were eligible for and participated in the study. Depending on their eligibility, respondents were first assigned to one of the three products (Similasan, Oscillococcinum, or Arnica) and then were randomly assigned to one of three or four package versions for that product (three versions each for Similasan and Oscillococcinum, four versions for Arnica — see next section for details). After they had viewed a 3-D image of the product, respondents answered a short questionnaire comprised of four closed-ended questions.

Package Versions

A total of ten mock-ups of packages for the three products were created as follows (see Appendix B for copies of fronts and backs of the ten package versions).

(1) Similasan:

Three mock-up packages were created for Similasan: original, homeopathy +, and disclosure #1. The original version was identical to the Similasan package available in the market. The homeopathy + version was identical to the original version except that the word "HOMEOPATHIC" at the top of the package front panel was made larger and more prominent. The disclosure #1 version was identical to the original version except that the statement "This product has not been shown to relieve cold symptoms" was introduced in red lettering in a black
box at the bottom of the back panel of the package.

(2) Oscillococcinum:

Three mock-up packages were created for Oscillococcinum: original, homeopathy +, and disclosure #1. The original version was identical to the Oscillococcinum package available in the market. The homeopathy + version was identical to the original version except that a second, more prominent "homeopathic" disclosure was added just above the brand name on the front panel. The disclosure #1 version was identical to the original version except that the statement "This product has not been shown to relieve flu-like symptoms" (in red lettering) replaced the contact information for the manufacturer at the bottom of the back panel of the package.

(3) Arnica 30X

Four mock-up packages were created for Arnica 30X: original, homeopathy +, disclosure #1, and disclosure #2. The original version was identical to the Arnica package available in the market with the exception that mentions of symptoms ostensibly treated by Arnica (in English and Spanish) as well as company contact information were removed from the back panel. The homeopathy + version was identical to the original version except that the word "HOMEOPATHIC" on the package front panel was made larger and more prominent, and the word "Hyland" (company name) was made smaller (to make room for the bigger "homeopathic" disclosure). The disclosure #1 version was identical to the original version except that the statement "Notice: This product has not been shown to relieve pain symptoms" (in red lettering) was added at the bottom of the back panel. The disclosure #2 version was identical to the original version except that the statement "Notice: The ingredients in this product have not been

---

2 These changes were necessary in order to fit the disclosure on the back panel of the package, even though it meant that the "original" version of the Arnica package used in the study was not identical to the version available in the market.

3 Thus, the wording and color of lettering for disclosure #1 was identical across the three products while the execution varied slightly.
tested for effectiveness" (in red lettering) was added at the bottom of the back panel.

The front, back, side and top/bottom panels for each of the ten package mock-ups were scanned, and the scanned pictures were used by Decision Analyst to create 3-D images for each of the ten packages. In the study, respondents could zoom in and rotate the 3-D images to look at all sides of a package (see below).

**Screening Procedure**

Screening questions were used to ensure that the respondents were in the target market for at least one of the three products (see Questions S1 through S4 in the interview protocol provided in Appendix C). To participate in the survey, respondents had to have purchased for themselves or for a family member one of the three product categories of interest (i.e., a product to relieve (a) cold symptoms for children aged 2-12, (b) pain, or (c) flu-like symptoms) within the past 12 months. In addition, respondents were excluded if they were under 18 or if they (or anyone in their household) worked in marketing research, a grocery or drug store, or for a drug or pharmaceutical company.

**Main Study Procedure**

The study questionnaire is included in Appendix C. Respondents were first given a practice task to familiarize them with relevant online tools and to ensure that they were following instructions carefully. They were shown a 3-D image of a bear and asked to zoom into the image and rotate it so that they could see all sides of the image. They were asked to identify the word/phrase written on the back of the bear. Respondents who were unable to do so were eliminated from the study.

Next, respondents were given the following scenario:

*T5: Assume that you are in your local drugstore or grocery store to purchase a product for yourself or a member of your family who is not feeling well. One of the products you*
see on display catches your eye, so you pick it up to look at it. This product is displayed on the next screen.

Respondents were then shown a 3-D image of one of the 10 versions of the three study products, and were told:

T6: Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the continue button when you are finished.

Next, respondents were asked a series of closed-ended questions pertaining to ad communication and beliefs/opinions. These questions are explained in the results section.

Soft Launch

Decision Analyst launched the survey and then shut it down after approximately 100 individuals had completed it in order to make sure everything was working properly. They identified no problems during this initial phase.

Results

After they had seen a 3-D image of one of the ten packages for the three products, respondents were first asked to identify the product (Q1A). Respondents who correctly identified the name of the product they had seen (Similasan, Oscillococcinum, or Arnica 30X) were asked the ensuing questions. Respondents who were unable to do so were eliminated from the study.

Respondents were next asked the following question:

Q1: Did or didn’t the package say or imply anything about relief of (symptoms associated with the common cold/aches and pains/symptoms associated with the flu), or don’t you know?

Table 1 shows the percentage of respondents who said “yes, it did” to this question for each of the products and package versions.
TABLE 14
(Q1: Did or didn’t the package say or imply anything about relief of (symptoms associated with the common cold/aches and pains/symptoms associated with the flu), or don’t you know? (% saying “yes, it did”))

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th>Disclosure 1</th>
<th>Disclosure 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Original (a)</td>
<td>Homeopathy + (b)</td>
<td>(c)</td>
<td>(d)</td>
</tr>
<tr>
<td>Similasan</td>
<td>88.5%</td>
<td>88.0%</td>
<td>90.9%</td>
<td>—</td>
</tr>
<tr>
<td>(n=175/175/175)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oscilloccinum</td>
<td>92.6%</td>
<td>88.0%</td>
<td>91.4%</td>
<td>—</td>
</tr>
<tr>
<td>(n=176/175/175)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arnica 30X</td>
<td>97.1%</td>
<td>96.0%</td>
<td>93.1%</td>
<td>93.8%</td>
</tr>
<tr>
<td>(n=175/177/175/176)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

These results show that a vast majority of respondents took away the appropriate “relief” claim associated with the product they saw. Also, for each of the three products, there was not a significant difference in the percentage of respondents who took away this claim across the three/four package versions.

Respondents who answered “yes” to Q1 were then shown the following:

T7: We are going to show you three statements about (Similasan/Oscilloccinum/Arnica 30X), one at a time. All, some, or none of these statements may be true. Please look at each statement and then indicate if you believe it is true, or you do not believe it is true, or you don’t know or are not sure.

They were then shown the following statements, one at a time, in random order:

Q2A1/A2/A3: A government agency like the Food and Drug Administration has approved (Similasan/Oscilloccinum/Arnica 30X) as being effective in relieving (symptoms associated with the common cold/symptoms associated with the flu/aches and pains).

Q2B1/B2/B3: The manufacturer of (Similasan/Oscilloccinum/Arnica 30X) has tested the product on people to show that it is effective in relieving (symptoms associated with the common cold/symptoms associated with the flu/aches and pains).

Q2C1/C2/C3: The American Medical Association has certified that

4 In this table as well as in subsequent tables, a letter in parenthesis within a cell indicates that that cell percentage was significantly different (at p<.05, two-tailed test) from the corresponding cell percentage in the column designated by the letter.
(Similasan/Oscillococcinum/Arnica 30X) is more effective than other remedies in relieving symptoms associated with the common cold/symptoms associated with the flu/aches and pains.

In the following tables and discussion, these three statements are abbreviated as (1) FDA approved, (2) Manufacturer tested, and (3) AMA certified. Responses to the FDA approved and Manufacturer tested statements are of focal interest in this study. The AMA certified statement was intended as a control statement designed to capture “yea saying.”

Table 2 shows, for each of the three products, the percentage of “yes, I believe that statement is true” responses to (1) the FDA approved statement, (2) the AMA certified statement (i.e., control statement), and (3) the FDA approved statement after the responses to the AMA certified statement have been netted out to control for “yea” saying:
TABLE 2
Responses to FDA approved statement, AMA Certified statement, and net responses
(% saying “yes, I believe that statement is true”)

<table>
<thead>
<tr>
<th></th>
<th>Original (a)</th>
<th>Homeopathy + (b)</th>
<th>Disclosure 1 (c)</th>
<th>Disclosure 2 (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similasan</td>
<td>56.0% (b, c)</td>
<td>38.9% (a)</td>
<td>44.6% (a)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>27.4%</td>
<td>28.0% (a)</td>
<td>25.7% (a)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>28.6%</td>
<td>10.9% (a, c)</td>
<td>18.9% (a, b)</td>
<td></td>
</tr>
<tr>
<td>Oscillococcinum</td>
<td>42.6% (c)</td>
<td>33.1% (a)</td>
<td>24.0% (a)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>22.7%</td>
<td>18.3% (a)</td>
<td>16.0% (a)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19.9% (c)</td>
<td>14.8% (b)</td>
<td>8.0% (a, b)</td>
<td></td>
</tr>
<tr>
<td>Arnica</td>
<td>32.6% (d)</td>
<td>32.2% (d)</td>
<td>23.4% (b)</td>
<td>19.9% (a, b)</td>
</tr>
<tr>
<td></td>
<td>22.3% (d)</td>
<td>15.8% (d)</td>
<td>16.0% (d)</td>
<td>12.5% (a)</td>
</tr>
<tr>
<td></td>
<td>10.3%</td>
<td>16.4% (c, d)</td>
<td>7.4% (b)</td>
<td>7.4% (b)</td>
</tr>
</tbody>
</table>

These results can be summarized as follows:

1. Between one-third and three-fifths of respondents exposed to the original product packaging indicated that they believed the FDA statement was true, i.e., that a government agency like the Food and Drug Administration had approved the product (Similasan, Oscillococcinum, or Arnica 30X) as being effective. (Range of responses across the three products: 32.6% to 56%).
For each product, a somewhat lower percentage of respondents exposed to the Homeopathy + product packaging indicated that they believed the FDA statement was true. (Range of responses across the three products: 32.2% to 38.9%). However, the difference was significant only for Similasan (56.0% versus 38.9%, p<.05 two-tailed).

Respondents showed less agreement with the FDA statement when exposed to the product packaging with disclosure #1 in comparison to the original packaging for all three products (two of three differences significant at p<.05).

Respondents showed less agreement with the FDA statement when exposed to the product packaging with disclosure #2 (tested for Arnica 30X only) in comparison to exposure to the original packaging (difference significant at p<.05).

To control for “yes” saying, affirmative responses to the FDA statement were adjusted by subtracting affirmative responses to the AMA statement for each of the three product/packaging versions. These adjusted responses indicate that:

After controlling for “yes” saying, between one-tenth and three-tenths of respondents exposed to the original product packaging indicated that they believed the FDA statement was true. (Range of responses across the three products: 10.3% to 28.6%).

For two of the three products, a somewhat lower percentage of respondents exposed to the Homeopathy + product packaging indicated that they believed the FDA statement was true. (Range of responses across the three products: 10.9% to 16.4%). However, the difference was significant only for Similasan (28.6% versus 10.9%, p<.05 two-tailed).

Respondents showed less agreement with the FDA statement when exposed to the product packaging with disclosure #1 in comparison to the original packaging for all three products (two of three differences significant at p<.05).
There was not a statistically significant difference in the level of agreement with the FDA statement when exposed to the product packaging with disclosure #2 in comparison to exposure to the original packaging (tested for Arnica 30X only).

Table 3 shows, for each of the three products, the percentage of "yes, I believe that statement is true" responses to (1) the Manufacturer tested statement, (2) the AMA certified statement (i.e., control statement), and (3) the Manufacturer tested statement after the responses to the AMA certified statement have been netted out to control for "yes" saying:

**Table 3**
Responses to Manufacturer tested statement, AMA Certified statement, and net responses (% saying "yes, I believe that statement is true")

<table>
<thead>
<tr>
<th></th>
<th>Original (a)</th>
<th>Homeopathy + (b)</th>
<th>Disclosure 1 (c)</th>
<th>Disclosure 2 (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Similasan</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n=175/175/175)</td>
<td>57.7%</td>
<td>52.6%</td>
<td>52.0%</td>
<td></td>
</tr>
<tr>
<td>- Manufacturer Tested Statement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- AMA Certified Statement</td>
<td>27.4%</td>
<td>28.0%</td>
<td>25.7%</td>
<td></td>
</tr>
<tr>
<td>- Net</td>
<td>30.3%</td>
<td>24.6%</td>
<td>26.3%</td>
<td></td>
</tr>
<tr>
<td><strong>Oscillococcinum</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n=176/175/175)</td>
<td>56.3%</td>
<td>54.9%</td>
<td>38.9%</td>
<td></td>
</tr>
<tr>
<td>- Manufacturer Tested Statement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- AMA Certified Statement</td>
<td>22.7%</td>
<td>18.3%</td>
<td>16.0%</td>
<td></td>
</tr>
<tr>
<td>- Net</td>
<td>33.6%</td>
<td>36.5%</td>
<td>22.9%</td>
<td></td>
</tr>
<tr>
<td><strong>Arnica</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n=175/177/175/176)</td>
<td>45.1%</td>
<td>49.2%</td>
<td>38.9%</td>
<td>38.1%</td>
</tr>
<tr>
<td>- Manufacturer Tested Statement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- AMA Certified Statement</td>
<td>22.3%</td>
<td>15.8%</td>
<td>16.0%</td>
<td>12.5%</td>
</tr>
<tr>
<td>- Net</td>
<td>22.8%</td>
<td>33.4%</td>
<td>22.9%</td>
<td>25.6%</td>
</tr>
</tbody>
</table>
These results can be summarized as follows:

(1) Between two-fifths and three-fifths of respondents exposed to the original product packaging indicated that they believed the Manufacturer tested statement was true, i.e., that the manufacturer had tested the product (Similasan/Oscillococcinum/Arnica 30X) on people to show that it is effective. (Range of responses across the three products: 45.1% to 57.7%).

(2) For each product, approximately the same percentage of respondents exposed to the Homeopathy + product packaging indicated that they believed the Manufacturer tested statement was true. (Range of responses across the three products: 49.2% to 54.9%).

(3) Respondents showed a lower level of agreement with the Manufacturer tested statement when exposed to the product packaging with disclosure #1 in comparison to the original packaging for all three products, but only one difference (for Oscillococcinum) was significant at p<.05.

(4) There was not a statistically significant difference in the level of agreement with the Manufacturer tested statement when exposed to the product packaging with disclosure #2 in comparison to exposure to the original packaging (tested for Arnica 30X only).

To control for “yea” saying, affirmative responses to the Manufacturer tested statement were adjusted by subtracting affirmative responses to the AMA statement for each of the ten product/packaging versions. These adjusted responses indicate that:

(5) After controlling for “yea” saying, between two-tenths and one-third of respondents exposed to the original product packaging indicated that they believed the Manufacturer tested statement was true. (Range of responses across the three products: 22.8% to 33.6%).
(6) Approximately the same percentage of respondents exposed to the Homeopathy + product packaging indicated that they believed the Manufacturer tested statement was true. (Range of responses across the three products: 24.6% to 36.5%).

(7) Respondents showed a lower level of agreement with the Manufacturer tested statement when exposed to the product packaging with disclosure #1 in comparison to the original packaging for two of three products, with one difference (for Oscillococcinum) significant at \( p < 0.05 \).

(8) There was not a statistically significant difference in the level of agreement with the Manufacturer tested statement when exposed to the product packaging with disclosure #2 (tested for Arnica 30X only) in comparison to exposure to the original packaging.

Finally, respondents were asked the following:

**Q3**: Did or didn’t the (Similasan/Oscillococcinum/Arnica 30X) package say that (Similasan/Oscillococcinum/Arnica 30X) is a homeopathic product, or don’t you know?

Table 4 shows the percentage of respondents who said “yes, it did” to this question for each of the products and package versions:

<table>
<thead>
<tr>
<th></th>
<th>Original (a)</th>
<th>Homeopathy + (b)</th>
<th>Disclosure 1 (c)</th>
<th>Disclosure 2 (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Similasan</strong></td>
<td>51.4% (b)</td>
<td>71.4% (a, c)</td>
<td>52.6% (b)</td>
<td>–</td>
</tr>
<tr>
<td>( n=175/175/175 )</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Oscillococcinum</strong></td>
<td>51.1% (b)</td>
<td>64.6% (a)</td>
<td>58.9% (b)</td>
<td>–</td>
</tr>
<tr>
<td>( n=176/175/175 )</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Arnica 30X</strong></td>
<td>60.9% (b)</td>
<td>79.7% (a, c, d)</td>
<td>58.3% (b)</td>
<td>58.0% (b)</td>
</tr>
<tr>
<td>( n=175/177/175/176 )</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
These results may be summarized as follows:

(1) Between half and six-tenths of respondents exposed to the original product packaging indicated that the package said that Similasan/Oscillococcinum Arnica 30X is a homeopathic product. (Range of responses across the three products: 51.1% to 60.9%).

(2) For each product, a significantly higher percentage of respondents exposed to the Homeopathy + product packaging indicated that the package said that Similasan/Oscillococcinum Arnica 30X is a homeopathic product. (Range of responses across the three products: 64.6% to 79.7%).

(3) For each product, there were no appreciable differences between respondents exposed to the original packaging and those exposed to packaging with disclosure #1 (for all three products) or disclosure #2 (for Arnica 30X only) on this measure.

**Conclusion**

The study results support the following conclusions in relation to the research questions that were presented earlier:

(1) Slightly more than half of all respondents exposed to the original product packaging correctly indicated that the packaging said that it is a homeopathic product. The range of correct responses across the three products was 51.1% to 60.9%.

(2) For all three products, exposure to packaging with the enhanced homeopathic disclosure (homeopathy +) significantly increased the number of respondents who indicated that the packaging said that it is a homeopathic product. Across the three products, the increase was in the range of 10% to 20%.

(3) After controlling for "yea" saying, between one-tenth and three-tenths of respondents...

---

5 The study did not include a control question for Q3; hence these percentages may be somewhat inflated due to "yea saying."
exposed to the original product packaging for the three products indicated that they believed that a government agency like the Food and Drug Administration had approved the products as being effective. (Range of responses across the three products: 10.3% to 28.6%).

(4) After controlling for “yea” saying, between two-tenths and three-tenths of respondents exposed to the original product packaging for the three products indicated that they believed the manufacturers had tested the products on people to show their effectiveness. (Range of responses across the three products: 22.8% to 33.6%).

(5) After controlling for “yea” saying, respondents showed significantly less agreement with the Manufacturer tested statement when exposed to the product packaging with disclosure #1 (“This product has not been shown to relieve cold/flu/pain symptoms”) in comparison to the original packaging for one of three products (Oscillococcinum). Thus, the beliefs listed under (4) were significantly weakened by the inclusion of this disclosure for one product only.

(6) After controlling for “yea” saying, there was not a statistically significant difference in the level of agreement with the Manufacturer tested statement when exposed to the product packaging with disclosure #2 (“The ingredients in this product have not been tested for effectiveness”) in comparison to exposure to the original packaging (tested for Arnica 30X only).\

---

6 The apparently limited effect of the two disclosures used in this study on beliefs could be due to a variety of factors, including lack of attention to, comprehension of, or reliance on the disclosure.
APPENDIX A

DECISION ANALYST ONLINE PANEL
American Consumer Opinion® Online is a proprietary, double opt-in panel of households that have agreed to participate in Internet surveys exclusively for Decision Analyst. The panel currently includes over eight million men, women, and children throughout the United States, Canada, Europe, Latin America, and Asia. Decision Analyst pays the highest incentives of any online panel to help ensure that it maintains a diverse, representative database of consumers, and to motivate its panelists to take the time necessary to provide the most accurate answers possible.

New panel members are continuously recruited by a combination of online and offline methods. The recruiting is designed to make the panel representative of the general adult population within each country. The major methods of recruiting include the following:

- Advertising on hundreds of websites
- Opt-in email lists
- Search engines
- Email newsletters and discussion lists
- Publicity and press releases
- Print advertising

The recruiting methods are designed to reach a broad cross-section of people, using a wide variety of sources, appeals, and websites. The Panel Administrator actively monitors the composition of the panel and adjusts recruiting methods and targets as needed to keep the panel balanced by major demographic variables. Panel recruiting is a constant, ongoing activity.

The panel is continuously cleaned and monitored to ensure the highest levels of accuracy and data integrity. Respondents who attempt to cheat are removed from the panel and blocked from rejoining the panel. Respondents who don't make a good faith effort to accurately answer open-end questions are deleted from the panel. Respondents who give the same answer repeatedly (among a list of attributes or statements) are deleted from the panel.

To achieve fully representative samples, Decision Analyst has developed its own advanced software (Iciron®) to draw stratified quota samples from the online panel that match the distribution of U.S. households by geography and demography. Samples can be pulled for a whole country, for individual states/provinces or sets of states/provinces, or for large metropolitan areas within states/provinces.
APPENDIX B

STUDY PRODUCT PACKAGES
Homeopathic Product Packaging Study
Package Mock-ups
10/17/11
Similasan

Cough Expectorant Syrup
Jarabe Expectorante

Multi-Symptom
Cough - Loosens Mucus - Fever
Chest & Head Congestion
Dye Free

100% Natural
Active Ingredients

Similasan

Cold & Mucus Relief™
Cough Expectorant Syrup
Jarabe Expectorante

Multi-Symptom
Cough - Loosens Mucus - Fever
Chest & Head Congestion
Dye Free

100% Natural
Active Ingredients
Homeopathy

Flu-like Symptoms
Feeling Run-Down • Headache • Body Aches • Chills • Fever

Oscillococcinum

No Side Effects • No Drug Interactions • Non-Drowsy

6 doses - 0.04 oz. each
HOMEOPATHIC MEDICINE

BOIRON®

Quick-Dissolving Pellets
### Oscillococcinum

**Back**

#### Drug Facts

<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nux vomica homeopathic to reduce the duration and severity of flu-like symptoms</td>
<td></td>
</tr>
</tbody>
</table>

The labels (HPUS) indicate that the ingredient in office is included in the Homeopathic Pharmacopoeia of the United States.

**Uses**

Temporarily relieve flu-like symptoms such as run down feeling, headache, body aches, chills and fever.

**Warnings**

Do not use if fluid content end caps are open or if this label seal is broken.

Ask a doctor before use in children younger than 2 years of age.

If symptoms persist or worsen, consult a healthcare professional.

### Directions

**Children younger than 2 years of age**

Ask a doctor.

**Other information**

• Store at 68-77°F (20-25°C) or 15-25°C in airtight container. Do not freeze.

### Efficacy

**Drug Facts**

<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nux vomica homeopathic to reduce the duration and severity of flu-like symptoms</td>
<td></td>
</tr>
</tbody>
</table>

The labels (HPUS) indicate that the ingredient in office is included in the Homeopathic Pharmacopoeia of the United States.

**Uses**

Temporarily relieve flu-like symptoms such as run down feeling, headache, body aches, chills and fever.

**Warnings**

Do not use if fluid content end caps are open or if this label seal is broken.

Ask a doctor before use in children younger than 2 years of age.

If symptoms persist or worsen, consult a healthcare professional.

### Directions

**Children younger than 2 years of age**

Ask a doctor.

**Other information**

• Store at 68-77°F (20-25°C) or 15-25°C in airtight container. Do not freeze.

### Inactive ingredients

• Strato, sucrose

This product has not been shown to relieve flu-like symptoms.
Arnica
Front

Original

Homeopathy

HOMEO PATHIC Arnica 30X

SPEED RECOVERY

HOMEOPATHIC Arnica 30X

SPEED RECOVERY

Bruising and Swelling  
Back Ache

Aches and Pains

Stiffness

Joint and Muscle Soreness

Bruising and Swelling  
Back Ache

Aches and Pains

Stiffness

Joint and Muscle Soreness
OTC Medicine Package Test

**STUDY INFORMATION:**
- Capture All Screening Data: Yes
- Landing Page: ACOP
- Disable Back Button: Yes
- Image Encryption: No

**SAMPLE SPECIFICATIONS:**
- Sample Source: ACOP
- Incentive: $5
- Description of Sample: US 50+ DC, Males and Females ages 18+. Exclude marketing, marketing research and advertising.

**SAMPLE/QUOTAS:**
- N=1,750

Each respondent will view and rate one package. Package images will be interactive 3D

**USE LEAST FILL TO ASSIGN TO ONE CELL/IMAGE WITHIN CELL**

- Quota 1: CELL 1 - SIMILASAN (COLD SYMPTOMS FOR CHILDREN, S1_1 = 1) n=525
  - Quota 2: 1a SIMILASAN IMAGE 1 (n=175)
  - Quota 3: 1b SIMILASAN IMAGE 2 (n=175)
  - Quota 4: 1c SIMILASAN IMAGE 3 (n=175)
- Quota 5: CELL 2 - ARNICA 30X (RELEVES PAIN, S1_2 = 1) n=700
  - Quota 6: 2a ARNICA IMAGE 1 (n=175)
  - Quota 7: 2b ARNICA IMAGE 2 (n=175)
  - Quota 8: 2c ARNICA IMAGE 3 (n=175)
  - Quota 9: 2d ARNICA IMAGE 4 (n=175)
- Quota 10: CELL 3 - OSCILLOCOCCINUM (FLU SYMPTOMS, S1_3 = 1) n=525
  - Quota 11: 3a OSC IMAGE 1 (n=175)
  - Quota 12: 3b OSC IMAGE 2 (n=175)
  - Quota 13: 3c OSC IMAGE 3 (n=175)

**DNQ1 - NONE OF S1_1, S1_2, OR S1_3 = CODE 1 (Haven't purchased medicine past 12 months)**

**DNQ2 - S2 = CODES 1-4 (SECURITY)**

**DNQ3 - S3 = CODE 1 (UNDER 18)**

**DNQ4 - S5 IS NOT CODE 3 (WAS NOT SEEN TREAT IMAGE)**

**DNQ5 - S6 IS NOT CODE 3 (DID NOT SEE WRITING ON BACK OF TREAT IMAGE)**

**DNQ998 - S7 NOT CODE 3 (CHEATER)**

**DNQ6 - Q1A INCORRECT PACKAGE SELECTED**

**QUESTIONNAIRE MAP**

Please enter your first name and email address in the boxes below.

(PAGE BREAK)
Dear [Insert Respondent (first_name)]:

Thanks for agreeing to complete this brief screening questionnaire.

As soon as you respond, your name will be entered into a drawing for $10,000 in monthly cash awards for participating in this screener. If your name is drawn, your account will be credited the following month. For example, if your name were to be drawn in May, your account would be credited during the first week of June.

Your individual answers will be anonymous and strictly confidential, of course. Once you have answered all of the questions on a page, please click on the "Continue" button.

Which of the following products, if any, have you purchased for yourself or for a member of your family in the last 12 months?

(Choose One Answer On Each Row Below)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1_1</td>
<td>A product to relieve cold symptoms for a child aged 2-12</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>S1_2</td>
<td>A product to relieve pain</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>S1_3</td>
<td>A product to relieve flu symptoms</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>S1_4</td>
<td>A product to relieve heartburn</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Do you, or does anyone in your household work...

(Choose All Correct Answers)

1 In marketing research
2 In advertising or public relations
3 For a grocery store or drugstore

Decision Analyst 2
4 For a drug or pharmaceutical company
5 None of these

(PAGE BREAK)

<table>
<thead>
<tr>
<th>S3</th>
<th>TYPE: Single Response</th>
<th>ALIAS: Age (18 to 75)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LOGIC/INSTRUCTIONS: MUST BE CODES 2-4, OTHERWISE DNG3</td>
<td></td>
</tr>
</tbody>
</table>

Are you...?
(Choose One Answer)
1 Under 18
2 18 to 34
3 35 to 54
4 55 or over

(PAGE BREAK)

<table>
<thead>
<tr>
<th>S4</th>
<th>TYPE: Single Response</th>
<th>ALIAS: Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LOGIC INSTRUCTIONS:</td>
<td></td>
</tr>
</tbody>
</table>

Are you?
(Choose One Answer)
1 Male
2 Female

(PAGE BREAK)

T17 TYPE: R/F

LOGIC INSTRUCTIONS: USES JAVASCRIPT CODE. (JAVASCRIPT CODE) (JAVASCRIPT CODE)

We would like for you to view a 3D image. Instructions are shown at the end of this paragraph to tell you how to rotate and zoom in on the image. Please make sure to rotate and zoom into the image to see all sides of it. After you finish viewing the image, click on the “Continue” button to continue.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left-Right Mouse Click on object and drag for Pan (JAVASCRIPT CODE) (JAVASCRIPT CODE)

(PAGE BREAK)

<table>
<thead>
<tr>
<th>S5</th>
<th>TYPE: Single Response</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LOGIC INSTRUCTIONS:</td>
</tr>
</tbody>
</table>

What 3D image, if any, did you see?
(Choose One Answer)
1 Horse
2 Bicycle
3 Teddy bear
4 Dog
5 Did not see anything
6 Received an error message
What was written on the back of the image?
(Choose One Answer)

1. Happy Birthday
2. Goodbye
3. Hello
4. I Love You
5. Did not say anything
6. Received an error message

For quality-control purposes, please select "Yellow" from the list below.
(Choose One Answer)

1. Red
2. Orange
3. Yellow
4. Green
5. Blue
6. Indigo
7. Violet

Thanks for completing this screening questionnaire. Your name has been entered into a drawing for $10,000 in monthly cash awards for participating in this screener. If your name is drawn, your account will be credited the following month. For example, if your name were to be drawn in May, your account would be credited during the first week of June.

You are invited to participate in the survey. It will take about 10 minutes to finish. Your incentive of [Insert Respondent (incentive_amount)] will be credited to your account within two weeks if you complete the following questionnaire by the date specified in our email.

Your individual answers will be anonymous and strictly confidential, of course. Once you have answered all of the questions on this page, please click on the "Continue" button.

Decision Analyst
Assume that you are in your local drugstore or grocery store to purchase a product for yourself or a member of your family who is not feeling well. One of the products that you see on display catches your eye, so you pick it up to look at it. This product is displayed on the next screen.

(PAGE BREAK)

Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the "Continue" button when you are finished.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left+Right Mouse Click on object and drag for Pan (JAVASCRIPT CODE) (JAVASCRIPT CODE)

Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the "Continue" button when you are finished.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left+Right Mouse Click on object and drag for Pan (JAVASCRIPT CODE) (JAVASCRIPT CODE)

Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the "Continue" button when you are finished.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left+Right Mouse Click on object and drag for Pan (JAVASCRIPT CODE) (JAVASCRIPT CODE)

Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the "Continue" button when you are finished.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left+Right Mouse Click on object and drag for Pan (JAVASCRIPT CODE) (JAVASCRIPT CODE)
Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the "Continue" button when you are finished.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left+Right Mouse Click on object and drag for Pan (JAVA SCRIPT CODE) (JAVA SCRIPT CODE)

Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the "Continue" button when you are finished.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left+Right Mouse Click on object and drag for Pan (JAVA SCRIPT CODE) (JAVA SCRIPT CODE)

Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the "Continue" button when you are finished.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left+Right Mouse Click on object and drag for Pan (JAVA SCRIPT CODE) (JAVA SCRIPT CODE)

Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the "Continue" button when you are finished.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left+Right Mouse Click on object and drag for Pan (JAVA SCRIPT CODE) (JAVA SCRIPT CODE)

Decision Analyst
Please look at the product shown below as you normally would. Take as much time as you need, and be sure to rotate and zoom in to see all sides of the package. Click the "Continue" button when you are finished.

Left Mouse Click on object and drag for Rotate
Right Mouse Click on object and drag for Zoom
Left+Right Mouse Click on object and drag for Pan (JAVA SCRIPT CODE) (JAVA SCRIPT CODE)

(PAGE BREAK)

What was the name of the product whose package you looked at? Was it...?

(Choose One Answer)
1 Similasan
2 Amicca 30X
3 Oscillococcinum
4 Don't know/Not sure

(PAGE BREAK)

Did or didn't the package say or imply anything about relief of{{gstrQ1 Insert}}, or don't you know?
(Choose One Answer)
1 Yes, it did
2 No, it did not
3 Don't know/Not sure

(PAGE BREAK)

We are going to show you three statements about{{gstrT71nset}}, one at a time. All, some, or none of these statements may be true. Please look at each statement and then indicate if you believe it is true, or you do not believe it is true, or you don't know or are not sure.

Click "Continue" to see the first statement.

(PAGE BREAK)
A government agency like the Food and Drug Administration has approved Similasan as being effective in relieving symptoms associated with the common cold. (Choose One Answer)
1 Yes, I believe that statement is true
2 No, I do not believe that statement is true
3 Don't know/Not sure

The manufacturer of Similasan has tested the product on people, to show that it is effective in relieving symptoms associated with the common cold. (Choose One Answer)
1 Yes, I believe that statement is true
2 No, I do not believe that statement is true
3 Don't know/Not sure

The American Medical Association has certified that Similasan is more effective than other cold remedies in relieving symptoms associated with the common cold. (Choose One Answer)
1 Yes, I believe that statement is true
2 No, I do not believe that statement is true
3 Don't know/Not sure

A government agency like the Food and Drug Administration has approved Amica 30X as being effective in relieving aches and pains. (Choose One Answer)
1 Yes, I believe that statement is true
2 No, I do not believe that statement is true
3 Don't know/Not sure
The manufacturer of Arnica 30X has tested the product on people, to show that it is effective in relieving aches and pains.

(Choose One Answer)

1 Yes, I believe that statement is true
2 No, I do not believe that statement is true
3 Don't know/Not sure

(PAGE BREAK)

The American Medical Association has certified that Arnica 30X is more effective than other remedies in relieving aches and pains.

(Choose One Answer)

1 Yes, I believe that statement is true
2 No, I do not believe that statement is true
3 Don't know/Not sure

(PAGE BREAK)

A government agency like the Food and Drug Administration has approved Oscillococcinum as being effective in relieving symptoms associated with the flu.

(Choose One Answer)

1 Yes, I believe that statement is true
2 No, I do not believe that statement is true
3 Don't know/Not sure

(PAGE BREAK)

The manufacturer of Oscillococcinum has tested the product on people, to show that it is effective in relieving symptoms associated with the flu.

(Choose One Answer)

1 Yes, I believe that statement is true
2 No, I do not believe that statement is true
3 Don't know/Not sure

(PAGE BREAK)

The American Medical Association has certified that Oscillococcinum is more effective than other flu remedies in relieving symptoms associated with the flu.

(Choose One Answer)
1 Yes, I believe that statement is true
2 No, I do not believe that statement is true
3 Don't know/Not sure

(PAGE BREAK)

Q3 TYPE: Single Response  ALIAS: Does the package say...

LOGIC INSTRUCTIONS: IF G3L 1 INSERT TEXT "SIMILASAN"
                    IF G3L 2 INSERT TEXT "ARNICA NOT" 
                    IF G3L 3 INSERT TEXT "COSULLCOCCCIUM"

Did or didn’t the (gstrQ3insert) package say that (gstrQ3insert) is a homeopathic product, or don’t you know?
(Choose One Answer)

1 Yes, it did
2 No, it did not
3 Don’t know/Not sure

(PAGE BREAK)

T3 TYPE: HTML  ALIAS: response name

LOGIC INSTRUCTIONS: [Insert Sample Details (contact_name)]
[Insert Sample Details (contact_title)]
[Insert Sample Details (panel_name)]
P.S. Please update your address and personal information if anything has changed since you joined
[Insert Sample Details (panel_name)]. Just go to our update page at [Insert Sample Details (website)].

(TABLE: not parsed)

(PAGE BREAK)

T4 TYPE: HTML  ALIAS: response name

LOGIC INSTRUCTIONS: [Insert Sample Details (confact_name)]
[Insert Sample Details (contact_title)]
[Insert Sample Details (panel_name)]

Thanks for completing this screening questionnaire.

Your name has been entered into a drawing for $10,000 in monthly cash awards for participating in this screen. If your name is drawn, your account will be credited the following month.

If you are selected to participate in the survey, we will notify you by email within one week.

Your answers and personal information are private, protected, and secure. (Privacy Policy: http://www.acop.com/PrivacyPolicy.aspx?L=1&PID)

If you have any questions about how the screening process works, please click here to view our FAQ page: http://www.acop.com/FAQ.aspx?L=1&PID=screening

Thanks for your help!

Decision Analyst
P.S. Please update your address and personal information if anything has changed since you joined [Insert Sample Details (panel_name)]. Just go to our update page at [Insert Sample Details (website)].