Comments of the Staff of the Federal Trade Commission[1]

Submitted to the Food and Drug Administration
Department of Health and Human Services

In Response to a 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

80 Fed. Reg. 16327 (Mar. 27, 2015)

Submitted on August 21, 2015

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 t Tc 5Tc -0fCD-3(e)4Aa5(t)-6(af)-1(f)]TJ 0 Tc 0 Tw 1.77 0 Td (")T

Quarter-Century.

[2] 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,[3] drug products must be approved by FDA or generally recognized as safe and effective. However, under the current regulatory

[1] These comments represent the views of the Division of Advertising Practices in the Federal Trade Commission's Bureau of Consumer Protection, the Federal Trade Commission's Bureau of Economics, and the Federal Trade Commission, and has voted to authorize the staff to submit t comments. Questions or comments concerning this document may be addressed to Gregory W. Fortsch Consumer Protection, Division of Advertising Practices, gfortsch@ftc.gov

or (202) 326-3617.

[2] 80 Fed. Reg. 16327.

[3] 21 U.S.C. § 321(g)(1)(A)-(C).

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

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.[12] To date, FDA has not reviewed this class of products for efficacy.[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.[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.[15] [illegible] For health, safety, or efficacy claims, the FTC has [illegible]

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.

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. -1(el)-6(i)-6(ab)-4s ceTht si3ab cu.3 Td [(pac Tc 0ul)-2(i)-2(Td (n)-4(f3(4(ecad)-4(i)-6(s

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.[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.[20] Similasan responded in an "Advertiser's Statement" that it was not required to have such evidence because the CPG did not require it.[21]

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

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.[25] 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.[26] 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.[27]

Two focus groups were conducted in Baltimore, Maryland in late 2010.[28] One focus group included eight adults while the other included eight parents.[29]

During the focus groups, the respondents were asked to discuss, among other things, the differences among conventional, herbal, and homeopathic products.[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.[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.[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.[33] Most parents and adults associated homeopathic products with natural or "non-chemical" products.[34]

Many adults and parents did not readily differentiate between evidentiary requirements and federal regulatory requirements for different types of products.[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.[36]

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[30] *Id.*
[31] *Id.* at 9.
[32] *Id.*
[33] *Id.* at 17.
[34] *Id.*
[35] *Id.* at 19.
[36] *Id.*

The focus group results also suggested that there is a poor understanding of the principles underlying homeopathic products.[37] 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.[38] 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.[39] 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.[40]

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.[41] 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.[42] 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.[43] 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.
Id. at 28.
[42] *Id.*
[43] *Id.*

lettering in a black box at the bottom of the back panel of the package.[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.[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 "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 "Notice: The ingredients in this product have not been tested for effectiveness" in red lettering was added at the bottom of the back panel.

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.[58] 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.[59] These results support the conclusion that consumers have incorrect perceptions about human efficacy testing for homeopathic products.[60]

C. Additional Observations

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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.