

'More food for thought' Advertising health food, drinks and supplements – what you can, can't and must say

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Introduction

One of the major reasons for the sudden surge in worldwide demand for health foods, drinks and dietary supplements is the generally proclaimed belief that dietary supplements are an inexpensive way of achieving balanced diets and improving and safeguarding the health of their users from potential diseases which may be caused by nutrition deficiency.

In a bid to enhance their market share, manufacturers of these dietary supplements employ various advertising and promotional activities to pique the interests of their target audiences. Advertising and promotion of dietary supplements thereby involves, but is not limited to, media adverts, product labelling, catalogues and direct marketing materials.

Many countries including Nigeria and the United States regulate dietary supplements as foods rather than drugs. Thus, the rules guiding the information permissible by regulatory agencies in these countries in respect to the advertisement and promotion of these products are generally simpler and more flexible.

This article will discuss the various agencies responsible for regulation of the advertisement and promotion of dietary supplements in Nigeria, and comparing it with what is obtainable in the US. It will

also highlight some of the major similarities and differences on what you can, cannot and must say when advertising and promoting dietary supplements in the US and Nigeria.

Nigeria

There are three agencies responsible for the regulation of the advertisement and promotion of dietary food supplements. They are:

- the National Agency for Food and Drug Administration and Control (NAFDAC);
- the Consumer Protection Council (CPC); and
- the Advertising Practitioners Council of Nigeria (APCON).

The National Agency for Food and Drug Administration and Control (NAFDAC)

NAFDAC regulates the manufacture, import, export, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, chemicals and packaged water in Nigeria. Dietary supplements are described as 'food for special dietary use' by the NAFDAC Guidelines.² Although every manufacturer or importer of dietary supplements in Nigeria is expected to consult with the Registration Division of NAFDAC before

importing or selling dietary supplements in Nigeria, no prior approval is needed.

NAFDAC is primarily responsible for regulating the information made available to customers on product labels. Dietary supplement labels are expected to be informative and accurate, indicating the name of the product and the address of the manufacturer together with the NAFDAC registration number, batch number, date of manufacture and 'best before' date.³ The net contents of essential ingredients ie, metric weight units in case of solids, semi-solids and aerosols and in the case of liquids, metric volume, must be clearly stated. In the case of foods, the ingredients must be listed by their common names in order of their predominance by weight unless the food is standardised, in which case the label must include only those ingredients which the standard makes optional. All food additives must be declared, spices and flavours may be listed as such, without naming the specific materials, but any artificial colours or flavourings must be properly identified.

NAFDAC makes nutritional labelling mandatory for any pre-packaged food item for which the manufacturer makes a nutritional or dietary claim.⁴ Any nutritional claim made on the label must be clearly justified by the manufacturer. All herbal medicinal products or food supplements (without established clinical studies) labels and advertising materials shall include the disclaimer 'these claims have not been evaluated by NAFDAC'. Where dietary supplements are labelled with claims of disease prevention, treatment, mitigation, cure or diagnosis in Nigeria, they will no longer be classified as food by NAFDAC and must comply with the guidelines for drugs and must be registered as medical products. The NAFDAC Guidelines permits a manufac-

turer to carry on consumer promotions for dietary supplements valid for a maximum of 15 weeks in Nigeria.

Consumer Protection Council (CPC)

The CPC is primarily responsible for overseeing compliance by manufacturers and importers of consumer goods with safety or health regulations in Nigeria. Every product manufactured, imported, advertised, sold or distributed in Nigeria must be registered with the CPC.⁵ The CPC has the statutory right to 'ban the sale, distribution, advertisement of products which do not comply with safety or health regulations'.⁶

The Regulations⁷ provides that all sales promotions must comply with Part 5 of the Nigerian Code of Advertising Practice and Sales Promotion ('the Code') which regulates advertising contents, sales promotion and direct marketing of products to consumers in Nigeria.

Advertising Standards Panel of the Advertising Practitioners Council of Nigeria (APCON)

The Advertising Standards Panel ('ASP'), a statutory Committee of APCON is primarily concerned with monitoring adverts and their compliance with the Code⁸ and the prevailing laws of Nigeria. Every advertiser must obtain advert approval from APCON before publishing any advertisement for dietary supplements as such adverts fall within the categories of products requiring pre-exposure clearance by the ASP. Upon approval, the adverts will be valid for one year from the date of approval.

The Code⁹ provides that adverts should not play on or exploit fear and distress in an attempt to induce patronage. Adverts should not contain any description, claim or illustration which directly or by implication conveys an

erroneous or misleading impression about the product or service advertised or about its suitability for the purpose recommended.

Any description, claim or illustration made in any advert of dietary supplements is subject to empirical proof and must be capable of substantiation. Advertisers of vitamins, minerals and other dietary supplements are expected to hold scientific evidence for any claim that their products are beneficial to health. No implied claims stating that the dietary supplements can be used to prevent or treat illness, elevate mood or enhance normal performance can be made in the adverts. Without well-established proof, no advert should suggest that there is a widespread vitamin or mineral deficiency or that it is necessary or therapeutic to use the products to augment a well-balanced diet. The advert must specify the target group (eg, women or athletes) to whom the advert is directed when claiming or implying that health may be maintained through the use of dietary supplements.

The United States of America

The Food and Drug Administration (FDA) and the Federal Trade Commission ('FTC') regulate the advertisement and promotion of dietary supplements. While the FDA regulates product labelling including packaging, inserts and other promotional materials distributed at the point of sale, the FTC regulates advertising claims, including print and broadcast advertisements, infomercials, catalogues and similar direct marketing materials as well as marketing on the internet.

US Food and Drug Administration (FDA)
The Dietary Supplement Health and Education Act (the 'DSHEA') of 1994

grants the FDA considerable powers to ensure the safety and accuracy of health claims made in respect of dietary supplements. The FDA's responsibility, however, does not start until the products get to the market. The onus of ensuring the safety of these products lies first with the manufacturer though it need not prove that the products are safe and effective prior to marketing them in the US. It, however, has the responsibility of ensuring that its products are safe and that the representations or claims made are substantiated by adequate evidence to show that they are not false or misleading. Manufacturers are also expected to register themselves with the FDA before selling or producing dietary supplements pursuant to the Bioterrorism Act of 2002.

By law, a dietary supplement advert can make three types of claims: health claims,¹⁰ nutrient content claims, and structure/function claims. The adverts can state that a dietary supplement addresses a particular nutrient deficiency, supports health or is linked to a particular health function if there is research to support the claim. Such a claim must be accompanied by a two-part disclaimer on the product label: 'This statement has not been evaluated by the US Food and Drug Administration (FDA)' and 'This product is not intended to diagnose, treat, cure or prevent any disease'.

The DSHEA also provides for certain exemptions from labelling requirements for dietary supplements. For instance, where scientific journal articles, books and other publications are used in the sale of dietary supplements, the information contained therein will be permissible provided the materials are reprinted in their entirety, are not false or misleading, do not promote a particular brand or manufacturer, are presented with other materials to create a balanced view of the

scientific information and is physically separate from the dietary supplements.

The Federal Trade Commission (FTC)

The FTC regulates dietary supplements advertising in the US. It requires that all information provided in the advert is truthful, not misleading and substantiated. All claims made in adverts by manufacturers of dietary supplements are subjected to FTC scrutiny. To ensure compliance with FTC laws, all express or implied claims conveyed by the advert to consumers must be properly identified and substantiated.

The onus of proving that adequate empirical evidence exists in support of the product claims rests with the manufacturers. The FTC evaluates the evidence presented and ensures that consumers have access to all the information needed to make an informed decision. The type of product, type of claims and consequences of a false claim determine the level of proof required from the manufacturer.

The FTC also requires the advertiser of dietary supplements to ensure that its adverts are not phrased or presented in such a way as to convey to the consumers an implied claim that its product is beneficial for the treatment of a disease.¹¹ Where the advertisement implies that there exists a disease benefit for a product that implied disease claim must be substantiated even where there is no express reference to the disease.

Advertisers are expected to disclose qualifying information where certain representations are suggested or made by an advert. These disclosures must be placed close to the claim being qualified and presented clearly on the advert in a way that is easily noticeable and understood by consumers. There are circumstances wherein disclosures are

needed to prevent the general public from being misled about the nature of the dietary supplements and the extent to which its safety and efficacy has been reviewed by the regulatory authorities. It should be noted however, that the inclusion of such a disclaimer or disclosure in a deceptive advertisement will not cure it of its deceptiveness particularly where the deception concerns the disease benefits of the product.

Under FTC rules, scientific evidence must exist to back up any underlying claims made by a consumer or expert endorser and should not be based on the honest opinion of the endorser. Consumer or expert endorsements must be backed by adequate substantiation stating clearly that the endorsement is representative of the general effect of the product on a consumer. Where this does not exist, a clear and conspicuous disclaimer will be necessary.

An advert can also contain claims which are based solely on the history of the use of the product for a particular purpose. Certain supplements derived from herbs like aloe vera, ginger, ginseng, garlic etc. have a long history of use for the treatment of various symptoms all over the world. Unlike many other countries, the US does not have in place a separate regulatory process for the approval of these claims made based on these traditional dietary supplements. What the FTC expects from advertisers in this scenario is that the adverts be carefully presented in a way that avoids the implication that the product has been scientifically evaluated for its efficacy.

The use of scientific articles, books and journals in advertising dietary supplements is acceptable to the FTC as long as there is no deception in the marketing of the products. These materials will only be subject to FTC jurisdiction where it is

established that the materials were created or used by an advertiser specifically for the purpose of promoting its product.

A comparison between Nigeria and the United States: What to say and what not to say

Generally, adverts of dietary supplements are meant to be as factual as possible when making claims as to their efficacy and effectiveness. Dietary supplements should not be advertised as an alternative

to healthy habits or prescription drugs, rather, it should be clearly portrayed as a supplement to healthy habits and prescription drugs. Dietary supplements must not be portrayed as a quick fix to a particular health issue. In Nigeria, NAFDAC and APCON particularly frown on adverts that portray certain dietary supplements as 'one size fit all'. The major similarities and differences in the kind of information permissible exist in the advertisement and promotion of dietary supplements are set out below.

ADVERTISEMENT AND PROMOTION OF DIETARY SUPPLEMENTS IN NIGERIA AND USA

DIFFERENCES

1. When making nutritional claims the FDA requires the disclaimer 'this product is not intended to diagnose, treat, cure or prevent any disease' to be included, NAFDAC is silent on this.
2. Manufacturers or importers are expected to consult with NAFDAC prior to selling the products in Nigeria while they are required to register with the FDA pursuant to the Bioterrorism Act of 2002.
3. The use of scientific journal articles, books etc. in the sale of dietary supplements is permitted by the FDA where certain conditions exist. NAFDAC is silent on this point.
4. The FTC requires advertisers to make qualifying disclosures in respect of certain representations suggested or made by an advert. APCON does not state this requirement.
5. The use of consumer or expert endorsements by advertisers is permissible by the FTC where it is backed by adequate substantiation. Nigerian law is silent on this.

SIMILARITIES

1. Nutrition labelling in the form of a 'supplement facts' panel is mandatory. In addition the FDA requires that the label must clearly state that it is a supplement.
 2. Nutritional claims must be clearly justified. A disclaimer that the claims have not been evaluated by NAFDAC or the FDA must be on the labels.
 3. No provisions in the law allow FDA or NAFDAC to 'approve' dietary supplements for safety or effectiveness before they reach the customers. Responsibility for safety lies with the manufacturer.
 4. Dietary supplements promoting the treatment, prevention or cure of a specific disease or condition on their labels are treated as unapproved and thus illegal drugs. Labelling must be consistent with the DSHEA and NAFDAC Guidelines.
 5. Both APCON and the FTC provide that all claims (express and implied) in an advert must be subject to empirical proof and must be substantiated. There should be no implied reference to treatment of a disease in an advert or promotion.
 6. The advert must specify the target group where an express or implied claim is made in respect to the maintenance of health through the use of dietary supplements.
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Notes

1. This article is based on Tomilola's paper, written as an entry for the Leisure Industries Section Scholarship competition for the IBA Annual Conference, Boston 2013.
2. Guidelines for the Registration of Food, Cosmetics, Medical Devices and Bottled Water in Nigeria; Guidelines for the Registration of Imported Food Products in Nigeria NAFDAC/RR/004/00.
3. *ibid*
4. Drugs and Related Products (Registration e.t.c) Act 1999 (as amended) Pre-Packaged Food (Labelling) Regulations 2005. Sec 18
5. Consumer Protection (Products and Services Monitoring and Registration) Regulations 2005
6. Consumer Protection Council Act CAP C25 LFN 2004 s.3
7. Consumer Protection Council Act 1992 Consumer Protection (Sales Promotions) Regulations 2005
8. *ibid*
9. Article 54 of the APCON Code of Advertising Practice and Sale
10. A health claim by definition has two essential components: 1. A substance (whether a food component or dietary ingredients); 2. A disease or health-related condition. The Nutrition Labeling and Education Act (NLEA) of 1990, the Food and Drug Administration Modernization Act of 1997 and the FDA's 2003 Consumer Health Information for Better Nutrition Initiative provide the FDA with a supervisory role in determining which health claims may be used on a label or in labelling dietary supplements.
11. Section 15, FTC Act.