



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. 2010 - 0008

MAR 18 2010

SUBJECT: Directive Specific to the Change in the Use of the Phrase "No Approved Therapeutic Claim" in all Advertisement, Promotional, and/or Sponsorship Activities or Materials concerning Food/Dietary Supplements.

I. RATIONALE/BACKGROUND

Article II, Section 15 of the 1987 Constitution expressly declares as a policy of the State to "*protect and promote the right to health of the people and instill health consciousness among them*". Pursuant to the above policy, Republic Act No. 3720, as amended by Executive Order (EO) No. 175, authorized and mandated the Department of Health, through the Food and Drug Administration to "*(a) Establish standards and quality measures for foods, drugs, and devices and cosmetics; and (b) Adopt measures to ensure pure and safe supply of foods and cosmetics, and pure, safe, efficacious and good quality drugs and devices in the country*"

Further, Republic Act No. 7394 or the Consumer Act of the Philippines reiterates the policy of the State to protect the interests of the consumers against deceptive, unfair and unconscionable sales acts or practices, misleading advertisements and fraudulent sales promotion practices; promote his general welfare; and to establish standards of conduct for business and industry. To achieve the above policies, the State, through its proper Department, was mandated to implement measures to protect the rights of consumers on matters against deceptive, unfair and unconscionable sales acts or practices and provide information and education to facilitate sound choice and the proper exercise of the rights by the consumer.

Recently, Republic Act No. 9711 or "*Food and Drug Administration (FDA) Act of 2009*", was enacted empowering the Food and Drug Administration under the Office of the Secretary to "*....prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about the health products as covered in the Act*"

While it is mandatory, pursuant to Bureau Circular No. 2 series 1992 and Memorandum Circular No. 25 series 1992, for every manufacturer, distributor or owner of food/dietary

supplements, as well as their agents to reflect the message or phrase "*No Approved Therapeutic Claim*" in every label, advertisements, promotions and other marketing materials for such products, the above message or phrase is, in one way or another, confuses the public particularly on the claims being used for a particular food/dietary supplement. More often, such phrase is being abused by the owners of such food/dietary supplements and/or their advertisers or agents. Corollary, a growing concern on food/dietary supplements with dubious, inaccurate, false, deceptive or misleading claims about their efficacy and/or nutritional, medicinal or health-enhancing attributes, character, value, merit, or safety are being raised by the members of the public, hence, this Administrative Order.

II PURPOSE AND OBJECTIVE

This Administrative Order is promulgated to provide directives specific to the change in the use of the message or phrase "*No Approved Therapeutic Claim*" in all advertisement, promotion and/or sponsorship activities or materials concerning Food/Dietary Supplements with the end view of promoting and protecting the consumers' health and welfare and fostering their right to proper information and education to facilitate sound choice.

III SCOPE

This Administrative Order shall cover the change of the use of the message or phrase "*No Approved Therapeutic Claim*" in all advertisement, promotion and/or sponsorship activities or materials concerning Food/Dietary Supplements, as well as, owners, manufacturers, distributors, advertisers and/or their agents of such products, and the Advertising Standards Council, Television Networks, Radio Stations and other concerned offices, establishments, or person.

For purposes of this Order, **Food/Dietary Supplement** shall mean a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, herb, or other botanical, amino acid, and dietary substance to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It usually is in the form of capsules, tablets, liquids, gels, powders or pills and not represented for use as a conventional food or as the sole item of a meal or diet or replacement of drugs and medicines.

IV DIRECTIVES

In issuing this Order, the Department of Health, through the FDA, hereby reiterates that it shall be unlawful for any person to disseminate or to cause the dissemination of any false, deceptive or misleading advertisement, promotion, or other marketing materials by Philippine mail or in commerce by print, radio, television, outdoor advertisement or other medium for the purpose of inducing or which is likely to induce directly or indirectly the purchase of a particular food/dietary supplement. An advertisement, promotion, sponsorship and other marketing materials in the various media of food/dietary supplements shall be deemed false, deceptive or misleading if it is not in conformity with the provisions of Republic Act No. 3720 as amended by Executive Order No. 175 and Republic Act No. 9711; and Republic Act No. 7394; as well as their respective rules and regulations issued thereto, or if it is misleading in a material respect, or if it is in violation of this Order.

A. Accordingly, the use of the message or phrase "*No Approved Therapeutic Claim*" shall no longer be allowed in any form of advertisement, promotion and/or sponsorship activities or materials concerning Food/Dietary Supplements commencing from the effectivity of this Order. Instead, the following rules shall apply:

1. All Food/Dietary Supplement owners, manufacturers, distributors, importers, exporters, advertisers, and/or their agents are mandated to strictly carry, *in Filipino*, the standard message or phrase;

"MAHALAGANG PAALALA: ANG (NAME OF PRODUCT) AY HINDI GAMOT AT HINDI DAPAT GAMITING PANGGAMOT SA ANUMANG URI NG SAKIT.

in every advertisement, promotion and/or sponsorship activities or any materials used concerning Food/Dietary Supplements.

2. For PRINT and other VISUAL advertisements, promotions, or materials, the above standard message or phrase shall be at least 1/3 of the size of the largest letter/logo and prominently (all in capital and bold letters) printed above of every advertisement, promotional activities or any materials used. Only the fonts Arial or Tahoma shall be used for the above standard message or phrase.

3. For AUDIO advertisements or promotions, the message or phrase

"MAHALAGANG PAALALA: ANG (NAME OF PRODUCT) AY HINDI GAMOT AT HINDI DAPAT GAMITING PANGGAMOT SA ANUMANG URI NG SAKIT.

shall be clearly and audibly voiced over, without being cut-off, in the last line of the advertisement or promotions regardless of its duration.

4. For AUDIO-VISUAL advertisements or promotions the above message or phrase in the preceding sub-paragraph (sub-paragraph 3) shall be clearly and prominently shown during the entire broadcast following the size and fonts established in sub-paragraph 2 above and clearly and audibly voiced over, without being cut-off, in the last line of the advertisement or promotion, regardless of the duration.

B. The Food and Drug Administration of the Department of Health— which has the primary jurisdiction on matters of advertisements of food/dietary supplements, the Advertising Standards Council, all Television Networks, Radio Stations and other relevant offices, establishments, or person shall require and see to it that every owner, manufacturer, importer distributor, advertiser and/or their agents, of Food/Dietary supplements strictly adhere to the above directives;

C. In addition, all Food/Dietary Supplement owners, manufacturers, distributors, advertisers, and/or their agents are mandated also to strictly observe at all times the following directives, *to wit*:

1. No person shall advertise, promote, or use in any sponsorship any food/dietary supplements unless such product is duly registered and approved by the Food and Drug Administration.
2. No person shall use in any advertising, promotion or sponsorship relating to such food/dietary supplement of any representation or suggestion that such food/dietary supplement is registered with the FDA when in fact it is not.
3. No claim shall be made in the advertisement, promotion and other marketing materials in the various media for use of any food/dietary supplements which is not contained in the label or approved by the FDA.
4. Any special claims must be substantiated and research results, scientific terms, statistics or quotations must be properly used, which must likewise be duly approved by the FDA prior to use in any advertisement, promotion and other marketing materials in the various media.
5. No person shall advertise, promote and use in any sponsorship any food/dietary supplement in any manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit, or safety.
6. Where a standard has been prescribed for a food/dietary supplement, no person shall advertise any food/dietary supplement in such a manner that is likely to be mistaken for such product, unless the food/dietary supplement complies with the prescribed standard or regulation.
7. No person shall make use of any reference to any laboratory report of analysis in the advertisement, promotion and use in other marketing materials in the various media of any food/dietary supplement, unless such laboratory report is duly approved by the FDA for use for such advertisement, promotion and other marketing materials in the various media.
8. No advertisement, endorsement or promotion of any food/dietary supplements shall be made by any medical practitioner or health worker, nor shall any owner, manufacturer, importer distributor, advertiser and/or their agents, of Food/Dietary supplements sponsor any activity, seminar, conference, or study of any medical practitioner or health worker.

D. All Food/Dietary Supplements advertised, promoted, and/or used in sponsorship activities that are not in compliance with or in violation of any of the sub-paragraph in either paragraphs A and C above shall be deemed misbranded and in violation of Republic Act No. 9711.

For this purpose, the FDA shall call upon any erring owner, manufacturer, distributor, or advertiser, and/or their agents to cease and desist outright from advertising, promoting and/or using in any sponsorship activity or material any Food/Dietary Supplement in question, without prejudice to any action of seizure by the FDA granted to it by Republic Act No. 9711. The applicable penalties as prescribed by the above law and regulations shall be imposed after notice and hearing.

V SEPARABILITY CLAUSE

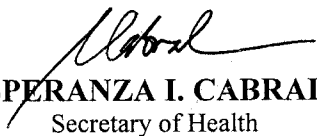
Should any of the provision(s) or part of this Order be declared unconstitutional, all other remaining portions not so declared shall remain valid and effective.

VI REPEALING CLAUSE

Any existing similar issuances relating to the rules or guidelines on the advertisement, promotion and/or sponsorship activities or materials concerning Food/Dietary Supplements that are inconsistent with this Order shall be deemed repealed or abrogated accordingly.

VII EFFECTIVITY

This Order shall take effect immediately after publication in two (2) national newspapers of general circulation.


ESPERANZA I. CABRAL, MD
Secretary of Health

수입제도 및 현안 모니터링 (수시)

('10년 10월 11일)

(싱가포르 aT)

구분	항 목	일자 및 출처	주 요 내 용	대처 및 처리방향
III.라벨링	1. 관련 정보 제공 2.라벨링 강화	2010년 7월 4일 GMA news	<p>□ 필리핀 보건부는 건강 보조제의 판매 관련 새로운 행정 명령 2010-0008 발효.</p> <p>□ 제품의 라벨은 특정 제품에 관한 소비자의 신념에 영향을 미칠 수 있고 잘못되거나 과장된 제품 설명은 소비자의 건강에 유해한 결과를 초래할 수 있어 필리핀 정부는 이에 관한 규제 중요성을 인식, 법령 및 규칙발표함.</p> <p>○ ‘의약품 승인 없음’의 기존 문구에서 필리핀어로 ‘이 제품은 의약품이 아니며, 질병 치료에 사용될 수 없다’라는 문구로 대체하여 반드시 기재하도록 하는 것이 주요 내용임.</p> <p>○ 필리핀 법령 7394 제 112조 (a), (b), 및 (c) / 필리핀 소비자 보호법 주요 조항:</p> <p>제112조(a) 해당제품의 성분 중 라벨에 표시되지 않았거나 관련 부처의 승인을 받지 않은 성분 광고 금지</p> <p>(b) 어떤 식품, 의약품, 화장품, 장치 또는 유해 물질을 허위 기재 또는 소비자를 현혹하거나 제품의 특성, 구성, 장점 또는 안전성에 관하여 오해의 소지가 있는 광고 금지.</p> <p>(c) 식품, 화장품 또는 장치에 관하여 기준을 기술할 경우,</p>	○ 라벨링 규정을 준수하여, 인삼/홍삼등 주요 건강 보조제 수출시 피해사례가 발생되지 않도록 주의 당부.

			<p>해당 제품의 표준 또는 규정에 관하여 기술되어 있지 않는 한 소비자가 제품에 관해 착각 소지가 있는 광고 게재가 금지됨.</p> <p>○ 이 행정 명령은 일반 건강 보조 제품에 모두 적용하며, FDA에 정식으로 등록 승인되지 않은 제품은 어떠한 광고나 협찬, 마케팅 활동을 할 수 없음.</p> <p>□ 인쇄 및 방송 지침</p> <p>○ 인쇄물과 시각적 광고의 경우, 가장 큰 글씨체의 1/3, 진하게, 대문자로 문구가 들어가야 한다.</p> <p>○ 오디오 광고의 경우, 해당 메시지가 명확하게 들려야 하며 방송 시간과 관계없이 생략되어서는 안됨.</p> <p>□ 벌금</p> <p>○ 허위 광고는 Republic Act 9711을 위반한 것으로 간주, 동법 11조에 의거, 위반자는 1년~10년 구형에 처하거나 5만 페소~50만 페소 벌금형에 처함.</p> <p>○ 위반자에게 위반품목의 가격 및 경제적 가치의 1% 또는 1000 페소의 추가벌금을 부과할 수 있으며, 지속적인 위반에 대하여 그 위반사항에 대해 일일 벌금을 추가 부과 가능.</p>	※ 필리핀 보건부 행정명령 2010-0008 영문 원문 별첨 참고.
--	--	--	--	---------------------------------------