Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

06 February 2015

FDA MEMORANDUM CIRCULAR
No. 2015-003

TO : **ALL FOOD/DIETARY SUPPLEMENT ESTABLISHMENTS, MASS AND SOCIAL MEDIA ADVERTISERS, ADVERTISING STANDARDS COUNCIL, TELEVISION AND MOBILE NETWORKS AND OTHER CONCERNED PARTIES**

Subject : **Reiteration of the FDA Requirement for the Change in the Use of the Message/Phrase "No Approved Therapeutic Claim" in Filipino as: "Mahalagang Paalala: Ang (Name of Product) ay Hindi Gamot at Hindi Dapat Gamiting Panggamot sa Anumang Uri ng Sakit" in all Advertisements, Promotional, and/or Sponsorship Activities or Materials**

The Court of Appeals, in its Decision of 28 November 2014, upheld DOH-FDA Administrative Order (AO) 2010-0008: Directive Specific to the Change in the Use of the Phrase, "No Approved Therapeutic Claim, in all Advertisements, Promotional, and/or Sponsorship Activities or Materials concerning Food/Dietary Supplements." The aforesaid Decision is hereby attached for reference.

As declared in the Court's Decision, *"the issuance of the AO is a but an exercise of the State's police power which cannot be hindered by property rights. As such right is innately ingrained in every State, there is no violation committed by the DOH when it issued the impugned AO which has for its end the health and welfare of the consuming public."*

In view of the above, FDA reiterates to all concerned food establishments, mass and social media advertisers as addressed as above; to comply with the directives stated in the said DOH Order, specifically:

1. 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.

2. 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."**

3. For audio advertisements or promotions, the message/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.

For strict compliance.

ATTY. NICOLAS B. LUTERO III, CESO III
OIC- Director IV, Food and Drug Administration

Republic of the Philippines
COURT OF APPEALS
MANILA

SPECIAL FOURTH (4th) DIVISION

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THE DEPARTMENT OF HEALTH, represented by Secretary Enrique T. Ona, M.D.,
Petitioner,

-versus-

CHAMBER OF HERBAL INDUSTRIES OF THE PHILIPPINES AND HONORABLE LUCIA P. PURUGGANAN, in her capacity as Presiding Judge of RTC Branch 30, Manila,
Respondents.

CA-G.R. SP NO. 119704

Members:

***GONZALES-SISON, M.,**
Acting Chairperson,
****YBAÑEZ, E. A., and**
SORONGON, *E.D. JJ.*

Promulgated:

NOV 28 2014

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DECISION

•SORONGON, E.D., *J.* :

This Petition for Certiorari under Rule 65 of the Rules of Court seeks to nullify and set aside the Orders of the Regional Trial Court

*Acting Chairperson per Office Order No. 485-14 -RSF dated November 24, 2014
**Acting Senior Member per Office Order No. 485-14 -RSF dated November 24, 2014

(RTC) of Manila, Branch 30 in Civil Case No. 10-123429 entitled *"Chamber of Herbal Industries of the Philippines vs. The Department of Health (DOH), represented by Secretary Enrique T. Ona, M.D."* The first assailed Order dated *May 28, 2010*[1] pertains to the issuance of the Writ of Preliminary Injunction prayed for by herein private respondent and the second assailed Order dated *September 30, 2010*[2] refers to the denial of herein petitioner's Motion to Dismiss and Urgent Motion to Dissolve the Preliminary Injunction.

The antecedent facts:

Private respondent, Chamber of Herbal Industries of the Philippines, is an association of over sixty five (65) companies in the Philippines engaged in the business of manufacture, development, research and distribution of herbal products. Under Section 10 of R.A. No. 3720, the Food and Drugs and Cosmetic Act, as amended by R.A. No. 9711, otherwise known as the Food and Drugs Administration Act of 2009, private respondents' herbal products are categorized and regulated as "food/dietary supplements" the distribution, marketing and labeling of which are subject to certain restrictions pursuant to the rules and regulations issued by the Food and Drug Administration as well as BFAD Circulars and Memorandum.

On March 18, 2010, petitioner Department of Health (DOH) under the then Secretary Esperanza I. Cabral issued *Administrative Order No. 2010-008*[3] *(AO)* setting forth 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[4]. The AO likewise mandates the change of the use of the message or phrase *"No*

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1 Rollo, pp. 38-41
2 Rollo, pp. 43-46
3 Rollo, pp. 76-80
4 Purpose and Objective, *Id.*

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 persons[5]. The AO was published on March 21, 2010 in the Philippine Star and the Philippine Daily Inquirer, two newspapers of general circulation.

On March 31, 2010 private respondent sent a letter[6] to DOH requesting it to consider as substantial compliance to the AO the phase: ***Mahalagang Paalala (Name of Product) Ay Hindi Gamot"***, insisting that the phrase would be more consistent with the registration of food supplements which is basically based on its supplementary or established health benefits[7]. A follow-up letter dated April 19, 2010[8] was made by private respondent reiterating their previous request and insisting that it has suffered and will continue to suffer great irreparable damage should the implementation of the AO be strictly enforced. On April 23, 2010 petitioner denied the said request[9].

Displeased, private respondent filed a Complaint for Injunction with prayer for Temporary Restraining Order (TRO) and/or Writ of Preliminary Injunction (WPI) on May 5, 2010 before the RTC of Manila. As earlier mentioned, the sought WPI was granted[10] by the RTC.

Subsequently, petitioner moved to dismiss the case[11] for lack of cause of action and further prayed that the WPI be dissolved[12]. However, by Order[13] dated September 30, 2010 the RTC also

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5 *Scope, Id.*
6 Rollo, pp. 82-83
7 *Id.*
8 Rollo, p. 84
9 Rollo, pp. 85-87
10 Supra at note 1
11 Petitioner's Motion to Dismiss, Rollo, pp. 112-126
12 Petitioner's Urgent Motion to Dissolve Preliminary Injunction, Rollo, pp. 127-136
13 Supra at note 2

denied it in this wise:

> *"In view of the foregoing, the dismissal of the case and the dissolution of the preliminary injunction are not in order. As for plaintiff's motion for the admission of its Amended Complaint, the same can, as it is hereby, granted for having been made before a responsive pleading by the defendant has been served to the former. The right granted to plaintiff under procedural law to amend the complaint before an answer has been served is not precluded by the filing of a motion to dismiss or any other proceeding contesting its sufficiency.*
>
> *WHEREFORE, premises considered, defendant's Motion to Dismiss and the Urgent Motion to Dissolve Preliminary Injunction are hereby DENIED. Plaintiff's Motion to Admit Amended Complaint is GRANTED. Defendant is given 15 days from receipt of this Order to file its Answer top the amended complaint.*
>
> *SO ORDERED."*

Hence, this special civil action for certiorari based on the grounds as follow:

> RESPONDENT JUDGE ACTED WITH GRAVE ABUSE OF DISCRETION AMOUNTING TO LACK OR EXCESS OF JURISDICTION IN GRANTING THE WRIT OF PRELIMINARY INJUNCTION.
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> NO CAUSE OF ACTION EXISTS AGAINST PETITIONER, CONSIDERING THAT ADMINISTRATIVE ORDER NO. 2010-0008 WAS ISSUED AS A VALID EXERCISE OF THE STATE'S POLICE POWER FOR THE PROTECTION OF HEALTH OF THE PUBLIC;
>
> PRIVATE RESPONDENT HAS NOT ESTABLISHED ANY CLEAR AND UNMISTAKABLE RIGHT THAT MUST BE URGENTLY PROTECTED FROM ADMINISTRATIVE

ORDER NO. 2010-0008;

RESPONDENT JUDGE COMMITTED AN ERROR IN PRESERVING THE STATUS QUO, DESPITE THE ABSENCE OF CONFLICT BETWEEN REPUBLIC ACT NO. 9711 AND REPUBLIC ACT NO. 8243.

The foregoing submissions can be simplified into two vital issues, to wit: ***(a) whether or not private respondent has a cause of action against petitioner; and (b) whether or not public respondent was correct in granting the injunctive relief prayed for by private respondent.***

It is an oft-cited rule that to determine the sufficiency of a cause of action, the facts alleged in the complaint should be considered, thus, the test of sufficiency of the facts alleged in a petition or complaint to constitute a cause of action is whether, admitting the facts alleged, the court could render a valid judgment upon the same in accordance with the prayer of the petition or complaint[14]. *"A cause of action exists if the following elements are present: (1) a right in favor of the plaintiff by whatever means and under whatever law it arises or is created; (2) an obligation on the part of the named defendant to respect or not to violate such right, and (3) an act or omission on the part of such defendant violative of the right of plaintiff or constituting a breach of the obligation of defendant to the plaintiff for which the latter may maintain an action for recovery of damages."*[15]

We agree with petitioner's contention that private respondent has no cause of action against it because the assailed AO was issued as a valid exercise of the police power of the State for the prevention and protection of the general public who has the right to be informed of the nature and established curative effects of food supplements they buy. The purpose of the AO is to educate consumers that food supplements are not medicines that can cure illness and that food supplements are not substitute for prescribed medicines. As cogently pointed out by the petitioner, the AO is reasonably necessary for the

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[14] Paranaque Kings Enterprises, Inc. vs. Court of Appeals, G.R. No. 111538, February 26, 1997
[15] *Id.*

public to be informed about what dietary supplements are.

The AO was issued by the DOH pursuant to Section 5/(O) of R.A. NO. 9711, thus, the Food and Drug Administration which is under the DOH has the power to prescribe standards, guidelines and regulations on marketing activities of health products. Thus:

> Section 5. Section 4 of Republic Act No. 3720, as amended, is hereby further amended to read as follow:
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> "SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) in the Department of Health (DOH). Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties;
>
> xxx xxx xxx
>
> "(o) 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 this Act;

Additionally, Article 21, Chapter II of Republic Act No. 7394 or the Consumer Act of the Philippines, empowers petitioner to regulate the advertisement of food and drug. Thus:

> ARTICLE 21. Implementing Agency. - In the implementation of the foregoing policy, the State, through the Department of Health, hereby referred to as the Department, shall, in accordance with the provision of this Act:
>
> a) establish standards and quality measures for food, drugs, devices and cosmetics;
>
> b) adopt measures to ensure pure and safe supply of foods and cosmetics, and safe, efficacious and good

quality of drugs and devices in the Country;

c) adopt measures to ensure the rational use of drugs and devices, such as, but not limited to, banning, recalling or withdrawing from the market drugs and devices which are unregistered, unsafe inefficacious or of doubtful therapeutic value, the adoption of an official National Drug Formulatory, and the use of generic names in the labeling of drugs;

d) strengthen the Bureau of Food and Drugs.

Further bolstering petitioner's function in relation to the subject AO is the principle that administrative agencies such as the DOH are equipped with necessary knowledge and expertise on their respective fields. As the Supreme Court ruled, the interpretation of the law by the government agency concerned is accorded great weight and consideration. Thus: *xxx In a catena of cases, we ruled that the construction given to a statute by and administrative agency charged with the interpretation and application of a statute is entitled to great respect and should be accorded great weight by the courts. The exception, which does not obtain in the present case, is when such construction is clearly shown to be in sharp conflict with the governing statute or the Constitution and other laws. The rationale for this rule relates not only to the emergence of the multifarious needs of a modern or modernizing society and the establishment of diverse administrative agencies for addressing and satisfying those needs, it also relates to accumulation of experience and growth of specialized capabilities by the administrative agency charged with implementing a particular statute*[16].

Petitioner's interpretation of how the disclaimer "No Approved Therapeutic Claim" should be delivered in the vernacular should be accorded great weight and respect, being the entity in charge of health-related matters. Verily, no cause of action exists against petitioner in the issuance of the subject AO which to emphasize is primarily aimed to inform the public that certain herbal products' therapeutic value has not been established, nothing more. Petitioner

[16] United Harbor Pilot's Association of hte Philippines, Inc. vs. Association of International Shipping Lines, Inc. 391 SCRA 522, 534 [2002].

acted in accordance with law and in recognition of the rights of the persons affected.

Now, on the propriety of the issuance of the WPI, We take a route different from the one taken by the RTC.

The issuance of a preliminary injunction is warranted under Section 3, Rule 58 of the Rules of Court which pertinently provides:

> *SEC. 3. Grounds for issuance of preliminary injunction. — A preliminary injunction may be granted when it is established:*
> *(a) That the applicant is entitled to the relief demanded, and the whole or part of such relief consists in restraining the commission or continuance of the act or acts complained of, or in requiring the performance of an act or acts, either for a limited period or perpetually;*
> *(b) That the commission, continuance or non-performance of the act or acts complained of during the litigation would probably work injustice to the applicant; or*
> *(c) That a party, court, agency or a person is doing, threatening or is attempting to do, or is procuring or suffering to be done, some act or acts probably in violation of the rights of the applicant respecting the subject of the action or proceeding, and tending to render the judgment ineffectual.*

The purpose of a preliminary injunction is to prevent threatened or continuous irremediable injury to some of the parties before their claims can be thoroughly studied and adjudicated. Its sole aim is to preserve the status *quo* until the merits of the case can be heard fully.[17] In fine, to be entitled to an injunctive writ, the petitioner has the burden to establish the following requisites:

> (1)*a right in esse or a clear and unmistakable right to be protected;*
> (2)*a violation of that right;*
> (3)*that there is an urgent and permanent act and*

[17] First Global Realty and Development Corporation vs. San Agustin, G.R. No. 144499, February 19, 2002

> *urgent necessity for the writ to prevent serious damage.*[18]

The trial court is given wide discretion in issuing the injunctive relief, notwithstanding, such discretion must be reasonably and soundly exercised and must still satisfy the strict requirements mandated by law. Should there be manifest abuse of such discretion the appellate courts will not hesitate to interfere to the issuance of the writ.

A review in the records shows that indeed, the RTC gravely abused its discretion in granting the WPI.

It bears to reiterate that private respondent has failed to meet the first requirement of a clear and unmistakable right, a right *in esse,* in order to be entitled to such injunctive relief. As elucidated above, the issuance of the AO is but an exercise of the State's police power which cannot be hindered by property rights. As such right is innately ingrained in every State, there is no violation committed by the DOH when it issued the impugned AO which has for its end the health and welfare of the consuming public.

Withal, the failure of the private respondent to make out a case to declare the unconstitutionality of AO No. 2010-0008, the WPI issued by the RTC certainly lacks basis.

WHEREFORE, the Petition is hereby **GRANTED**. The Orders of the Regional Trial Court of Manila, Branch 30 dated *May 28, 2010* and *September 30, 2010* are hereby **SET ASIDE**. Accordingly, the complaint below is **DISMISSED** for utter lack of merit and the Writ of Preliminary Injunction is **LIFTED** and **DISSOLVED**.

SO ORDERED.

EDWIN D. SORONGON
Associate Justice

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[18] Tayag vs. Lacson, G.R. No. 134971,March 25, 2004

WE CONCUR:

MARLENE GONZALES-SISON
Acting Chairperson

ELIHU A. YBAÑEZ
Acting Senior Member

CERTIFICATION

Pursuant to Article VIII, Section 13 of the Constitution, it is hereby certified that the conclusions in the above decision were reached in consultation before the case was assigned to the writer of the opinion of the Court.

MARLENE GONZALES-SISON
Acting Chairperson
Special Fourth (4th) Division