

**Republic of the Philippines
HOUSE OF REPRESENTATIVES
Constitution Hills, Quezon City**

**Sixteenth Congress
First Regular Session**



HOUSE BILL NO. 4620

Introduced by Representative Catherine Barcelona-Reyes, M.D.

EXPLANATORY NOTE

As a state policy, the 1987 Philippine Constitution has adopted the right to health of the people. This is embodied in Section 15, Article II of the 1987 Philippine Constitution. The people are the strength of the nation; thus, the State must place the welfare of the people at the top of its priorities. Subsumed in the welfare of the people is their health. The State shall do everything to protect the health of its people.

This bill seeks to implement Article II, Section 15 of the 1987 Philippine Constitution by informing the people of the difference between drugs, which are stamped with an approval of therapeutic claim by the Food and Drug Administration, and food/dietary supplements, which are not given such approval. This can only be done by printing disclaimers on the packaging of food/dietary supplements that effectively give the message that these do not have any proven therapeutic claim.

The State promotes the right to health of the people through this act by ensuring that the people are properly informed that these food/dietary supplements have no proven therapeutic claim. Given an informed choice, the people may then know to which they must allocate their resources – either to proven drugs or to non-proven food/dietary supplements –

in the event that they should get sick. Given an informed choice, the people will know the difference between these two products.

The passage of this legislative measure is earnestly sought.



HON. CATHERINE BARCELONA-REYES, M.D.
First District, Camarines Norte
Representative

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AN ACT
TO ENSURE HEALTH PROTECTION THROUGH VISIBLE
DISCLAIMERS ON FOOD/DIETARY SUPPLEMENTS PACKAGING/BOTTLES

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

Section 1. Short title. This Act shall be known as “The Expanded No-Approved-Therapeutic-Claim Label Act of 2014”

Section 2. Declaration of Principles. The State shall protect and promote the right to health of the people and instill health consciousness among them. The State shall also protect consumers from trade malpractices and from hazardous products.

Section 3. Purpose. The purpose of this Act is to ensure that:

- a. Disclaimers on dietary supplements effectively are very visible enough to inform the people of the lack of any approved therapeutic claim on the part of these supplements.
- b. Packaging of food/dietary supplements do not mislead the people into believing that these have the same proven effects of drugs which are approved by the Food and Drug Administration.

Section 4. Definitions of Terms.

- a. "Disclaimer" means warning labels specified under Section 5 of this Act that inform the people that food/dietary supplements do not have an approval of therapeutic claim by the Food and Drug Administration.
- b. "Food/dietary supplements" mean products registered as such which are not given an approval of therapeutic claim by the Food and Drug Administration.
- c. "Display surface" pertains to the packaging of food/dietary supplements.

Section 5. Disclaimer. Within one-hundred twenty (120) days from the effectivity of this Act, food/dietary supplements found in the market shall bear, in a highly visible font and print and in both English and Filipino, the phrase, "NO APPROVED THERAPEUTIC CLAIM BY THE FOOD AND DRUG ADMINISTRATION. THIS MANUFACTURED PRODUCT HAS NO SCIENTIFICALLY-PROVEN HEALTH BENEFIT" as prescribed herein:

- a. The disclaimer shall be printed on at least fifty percent (50%) of the display surface of these food/dietary supplements.
- b. Nothing shall be printed on the location prescribed where it is likely to obscure or cover the disclaimer, in part or in whole.
- c. The disclaimer shall be printed in a highly visible font in capital letters, both in English and Filipino.

Section 6. Costs. All printing costs for the disclaimer on food/dietary supplements shall be shouldered by the manufacturers.

Section 7. Prohibition on Sale. No person or legal entity shall sell or commercially distribute or display any food/dietary supplement without ensuring that the packaging meets the disclaimer requirement under this Act.

Section 8. Penalties for Non-Compliance.

- a. The following penalties shall apply to manufacturers, importers, and exporters of food/dietary supplements for failure to comply with Section 5 of this Act or any violation of this Act:

-On the first offense, a fine of not more than Five-Hundred Thousand Pesos (P500,000) shall be imposed;

-On the second offense, a fine of One Million Pesos (P1,000,000) shall be imposed;

-On the third offense, both a fine of Two Million Pesos (P2,000,000) and imprisonment of not more than one year. The business permits and licenses, in the case of a business entity or establishment shall also be revoked or cancelled.

If the guilty officer is an alien, he shall be summarily deported after the finding of probable cause on the second offense and shall be forever barred from re-entering the Philippines.

- b. The following penalties shall apply to distributors and retailers of food/dietary supplements as well as their agents for failure to comply with Section 7 or for any violation of this Act:

On the first offense, a fine of not more than One Thousand Five Hundred Pesos (P1,500) shall be imposed;

On the second offense, a fine of Five Thousand Pesos (P5,000) shall be imposed;

On the third offense, either a fine of not more than Ten Thousand Pesos (P10,000) but not less than Five Thousand Pesos (P5,000), or imprisonment of not more than one year, or both at the discretion of the court. The business permits and licenses, in the case of a business entity or establishment shall also be revoked or cancelled.

If the guilty officer is an alien, he shall be summarily deported after the finding of probable cause on the second offense and shall be forever barred from re-entering the Philippines.

Section 9. Administrative Power. The Department of Health is hereby charged with the implementation and enforcement of the provisions of this Act. Within six (6) months from the effectivity of this Act, the Department of Health shall formulate guidelines and

regulations to facilitate the implementation of this Act. The Department of Health, through the Philippine Food and Drug Administration, is hereby authorized to:

- a. Promulgate rules governing the hearings on alleged violations of this Act. The hearings shall be summary in nature and shall be conducted by means of position papers and affidavits. Decisions must be rendered by the Department of Health no longer than thirty (30) days after filing.
- b. Impose, after due notice and hearing, fines of up to Five Million Pesos (P5,000,000), the proceeds of which will be used for health promotion campaigns of the Department of Health.

Section 10. Separability Clause. If any clause, provision, paragraph, or part thereof shall be declared unconstitutional or invalid, such judgment shall not affect, invalidate, or impair any other part thereof but such judgment shall merely be confined to such clause, provision, paragraph or part directly involved in the controversy in which such judgment has been rendered.

Section 11. Repealing Clause. All other laws, decrees, executive orders and other administrative issuances and parts thereof which are inconsistent with the provisions of this Act are hereby modified, superseded, or repealed accordingly.

Section 12. Effectivity. This Act shall take effect fifteen (15) days following its publication in the Official Gazette or in a major daily newspaper of national circulation in the Philippines.

Approved.