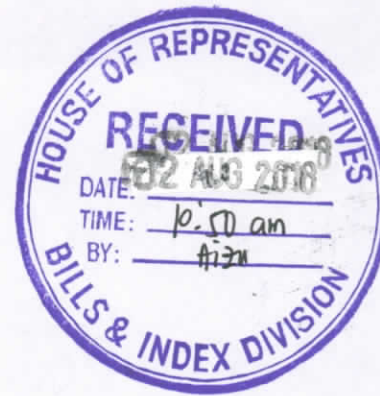


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

SEVENTEENTH CONGRESS
Third Regular Session

House Bill No. 8002



Introduced by REPRESENTATIVE ARTHUR C. YAP

EXPLANATORY NOTE

The Philippines, being identified as one of the countries with the most diverse natural resources, has an important stake in the development of its own alternative medicines, particularly those derived from plant sources. The Food and Drug Administration (FDA) is the government agency which has the regulatory power over the production, distribution and use of these health products.

According to a research article written by Yolanda Robles et al and published in the Journal of Asian Association of Schools of Pharmacy, the traditional medicine (TM) and herbal supplement (HS) industry can learn from other countries with highly developed regulatory systems for such products. The proliferation of unregistered products of variable quality must be tackled by a more rigorous regulation of the government in the interest of public safety. This present need is even more compounded by the recent movement towards harmonizing regulatory processes among ASEAN countries. The Philippines must be prepared to bring to the regional forum those policies which protect the regional and national interests while being sensitive to the concerns of the local herbal industry and the Filipino people.

The alignment of FDA regulations and provisions of RA 8423, otherwise known as the Traditional and Alternative Medicine Act (TAMA), is envisioned to strengthen the position of the local food supplement and herbal medicine industry in responding to the country's health needs.

However, despite the new FDA law (RA 9711) being passed, there is no single unit dedicated to the screening, evaluation and processing of technical documents and other regulatory requirements for these group of products. They are either processed with applications for conventional medicines or with applications for food items.

The creation of a center exclusively devoted to traditional and alternative under the FDA will streamline and expedite registration procedures to facilitate the release of product registration certificates. Similar to other centers, it shall also be headed by a director with the following divisions:

- i. Licensing and Registration Division, which shall be responsible for evaluating health products and establishments as covered by this Act for the purpose of issuance of authorizations and conditions to be observed;
- ii. Product Research and Standards Development Division, which shall be responsible for the conduct of research, development of standards and regulations, compliance monitoring, and the oversight and audit of related researches that would ensure safety, quality, purity and efficacy of health products, as covered in this Act; and
- iii. Laboratory Support Division, which shall be responsible for the conduct of research and appropriate tests and calibration, analyses and trials of products including, but not limited to, assays, and the conduct of oversight and/or audit of centers conducting bioavailability and bioequivalence tests and other tests as covered by this Act. It shall likewise provide direct line support to the centers which shall be separate and distinct per major product category that is regulated.

The composition will include experienced researchers on traditional medicines, FDA clerical staff, and practitioners of TM/HS with no competing interests. Alternative medicine practitioners or certified herbalists should be chosen to be part of evaluation teams, instead of medical doctors and conventional medicine practitioners.

As for the scientific validity criteria, the minimum requirements for establishing the claims of TM and HS should include at least chemical tests to prove the presence of constituents responsible for the claims made.

In view of the foregoing, immediate passage of this bill is earnestly sought.



Hon. ARTHUR C. YAP
Representative
3rd District, Bohol

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

SEVENTEENTH CONGRESS
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AN ACT
AMENDING REPUBLIC ACT 9711, OTHERWISE KNOWN AS THE
"FOOD AND DRUG ADMINISTRATION ACT" AND FOR OTHER
PURPOSES

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

1 **SECTION 1.** Section 6 of Republic Act No. 9711, as amended, is hereby
2 further amended and new subsections are added to read as follows:

3 "SEC. 5. The FDA shall have the following centers and offices:

4 "(a) The Centers shall be established per major product category that is
5 regulated, namely:

6 "(1) Center for Drug Regulation and Research (to include
7 veterinary medicine, vaccines and biologicals);

8 "(2) Center for Food Regulation and Research;

9 "(3) Center for Cosmetics Regulation and Research (to include
10 household hazardous/urban substances); and

11 "(4) Center for Device Regulation, Radiation Health, and
12 Research.

13 “(5) CENTER FOR TRADITIONAL AND ALTERNATIVE
14 MEDICINE.

15 "These Centers shall regulate the manufacture, importation, exportation,
16 distribution, sale, offer for sale, transfer, promotion, advertisement,
17 sponsorship of, and/or, where appropriate, the use and testing of health
18 products. The conduct research on the safety, efficacy, and quality of
19 health products, and to institute standards for the same.

20 "(b) Each Center shall be headed by a director. The Centers shall be so
21 organized such that each will have, at least, the following divisions:

1 "(1) Licensing and Registration Division, which shall be responsible for
2 evaluating health products and establishments as covered by this Act for
3 the purpose of issuance of authorizations and conditions to be observed;

4 "(2) Product Research and Standards Development Division, which shall
5 be responsible for the conduct of research, development of standards and
6 regulations, compliance monitoring, and the oversight and audit of
7 related researches that would ensure safety, quality, purity and efficacy
8 of health products, as covered in this Act; and

9 "(3) Laboratory Support Division, which shall be responsible for the
10 conduct of research and appropriate tests and calibration, analyses and
11 trials of products including, but not limited to, assays, and the conduct of
12 oversight and/or audit of centers conducting bioavailability and
13 bioequivalence tests and other tests as covered by this Act. It shall
14 likewise provide direct line support to the centers which shall be separate
15 and distinct per major product category that is regulated.

16 SECTION 2. Implementation. - The FDA, in coordination with PITAHC,
17 shall issue implementing rules and regulations as may be necessary to carry out
18 the purpose of this Act within ninety (90) days from effectivity hereof.

19 SECTION 3. Separability Clause. - The provisions of this Act are hereby
20 declared separable. If any portion thereof shall be held invalid unconstitutional,
21 such invalidity or unconstitutionality shall not affect the other provisions which
22 shall remain in full force and effect.

23 SECTION 4. Repealing Clause. - All laws, executive orders, letters of
24 instructions, rules and regulations, or provisions thereof, which are inconsistent
25 with the provisions of this Act are hereby repealed, amended or modified
26 accordingly.

27 SECTION 5. Effectivity Clause - This Act shall take effect within fifteen (15)
28 days after its complete publication in the Official Gazette or in at least two (2)
29 newspapers of general circulation.