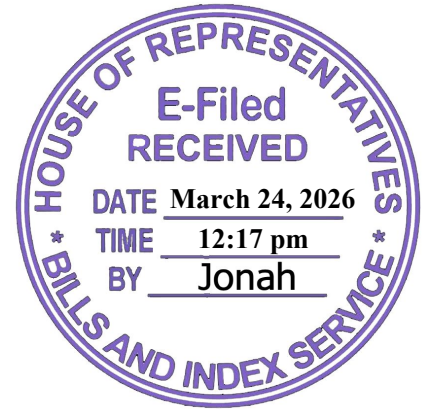


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Constitution Hills, Quezon City

TWENTIETH CONGRESS
First Regular Session

House Bill No. 8755



Introduced by: **REPRESENTATIVE ERIC L. OLIVAREZ**

EXPLANATORY NOTE

The rapid expansion of e-commerce has significantly improved access to goods and services, including health products. However, it has also facilitated the proliferation of counterfeit, unregistered, adulterated, and otherwise unsafe health products sold through online platforms, posing serious risks to public health and safety.

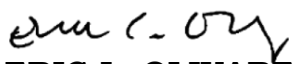
While Republic Act No. 9711 (Food and Drug Administration Act of 2009) and Republic Act No. 11967 (Internet Transactions Act) provide important regulatory frameworks, gaps remain in addressing the unique challenges of online health product transactions. In particular, there is a need for clearer regulatory authority, stronger enforcement mechanisms, and defined accountability for digital platforms that enable such transactions.

This bill seeks to strengthen the regulatory framework by reinforcing the authority of the Food and Drug Administration (FDA) over online health product transactions, in coordination with relevant agencies. It imposes enhanced obligations on digital platforms, including verification of FDA authorizations, monitoring of listings, traceability, and timely takedown of violative products.

The measure likewise establishes platform accountability by providing for solidary liability with sellers upon a showing of fault or negligence, ensuring that platforms that allow or fail to act against the sale of illicit health products may be held accountable.

By strengthening and harmonizing Republic Act No. 9711 and Republic Act No. 11967, this measure promotes a safer and more accountable digital marketplace for health products and upholds the State's duty to protect public health.

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


ERIC L. OLIVAREZ

Republic of the Philippines
HOUSE OF REPRESENTATIVES
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TWENTIETH CONGRESS
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House Bill No. 8755

Introduced by: **REPRESENTATIVE ERIC L. OLIVAREZ**

**“AN ACT
STRENGTHENING THE REGULATION OF ONLINE TRANSACTIONS
INVOLVING HEALTH PRODUCTS, EXPANDING THE POWERS OF THE
FOOD AND DRUG ADMINISTRATION UNDER REPUBLIC ACT NO.
9711, AND ENHANCING REPUBLIC ACT NO. 11967 (INTERNET
TRANSACTIONS ACT), IMPOSING LIABILITY ON DIGITAL
PLATFORMS, AND FOR OTHER PURPOSES”**

SECTION 1. Short Title. - This Act shall be known as the “Online Health Products Safety and Accountability Act.”

SECTION 2. Declaration of Policy. - It is the policy of the State to:

- a. Protect the public from unsafe, counterfeit, adulterated, falsified, unregistered, and violative health products sold through digital platforms;
- b. Ensure that online commerce involving health products is subject to the same or higher level of regulatory control as physical distribution;
- c. Strengthen the authority of the Food and Drug Administration (FDA) as the primary regulatory authority over health products in online transactions;
- d. Enhance Republic Act No. 11967 (Internet Transactions Act) by establishing heightened obligations and liabilities for digital platforms engaged in health product commerce.

SECTION 3. Scope and Coverage. - This Act shall apply to all health products regulated under Republic Act No. 9711, including:

- a. Food
- b. Drugs and medicines
- c. Biological products and vaccines

- d. Medical devices
- e. In vitro diagnostic products
- f. Cosmetics
- g. Veterinary drugs and products
- h. Household/urban hazardous substances regulated by the FDA

This Act shall not apply to non-FDA-regulated consumer goods.

SECTION 4. Definition of Terms. - For purposes of this Act:

- a. **Online Health Product Transaction** – Any act of offering, listing, advertising, selling, distributing, or facilitating the sale of FDA-regulated health products through electronic, digital, or online means.
- b. **Digital Platform** – Any online marketplace, e-commerce platform, website, application, social media platform, or intermediary service that enables or facilitates online health product transactions.
- c. **Illicit Health Products** – Health products that are counterfeit, falsified, adulterated, misbranded, unregistered, expired, recalled, prohibited, or otherwise violative of FDA laws and regulations.
- d. **Platform Operator** – Any natural or juridical person that owns, controls, manages, or operates a digital platform accessible to Philippine consumers.

SECTION 5. Primary Regulatory Authority. - The Food and Drug Administration (FDA) shall have primary jurisdiction over the regulation of health products in online transactions and shall exercise such authority in coordination with relevant government agencies, including but not limited to the Department of Trade and Industry (DTI), Department of Information and Communications Technology (DICT), and the National Telecommunications Commission (NTC).

The FDA shall have the authority to:

- a. Regulate online health product transactions;
- b. Supervise, inspect, investigate, and monitor digital platforms selling health products;
- c. Issue binding compliance orders, takedown orders, cease-and-desist orders, and platform sanctions;
- d. Impose administrative penalties and recommend criminal prosecution.

All powers granted under this Act shall be in addition to those already provided under Republic Act No. 9711.

SECTION 6. Enhanced Obligations of Digital Platforms. - In addition to obligations under Republic Act No. 11967, digital platforms that allow the sale of FDA-regulated health products shall be required to:

- a. Seller and Product Verification-** Verify FDA authorizations (CPR, LTO, CMDR, and other relevant certifications) prior to listing; Prohibit listings of health products without valid FDA approval.
- b. Continuous Compliance Monitoring-** Implement automated and manual monitoring systems to detect illegal health products; Prevent relisting of previously removed violative products or sellers.
- c. Traceability and Recordkeeping-** Maintain transaction, seller, and product records for at least five (5) years, accessible to the FDA upon lawful request.
- d. Immediate Takedown Obligation-** Remove or disable access to violative listings within a reasonable period not exceeding forty-eight (48) hours, upon FDA notice, unless a shorter period is required due to imminent public health risk, and without the need for a prior court order as may be allowed by law.
- e. Consumer Notification-** Notify affected consumers of:
 - i. FDA advisories
 - ii. Product recalls
 - iii. Safety alerts
 - iv. Enforcement actions

SECTION 7. FDA Emergency Powers Over Online Platforms - Where public health is at imminent risk, the FDA may:

- a. Order immediate takedown of listings or specific platform sections;
- b. Recommend to appropriate government agencies the restriction of access to non-compliant platforms;
- c. Freeze digital listings and online advertisements pending investigation.

All actions under this section shall be exercised subject to due process and in coordination with appropriate government agencies.

SECTION 8. Platform Liability - Digital platforms may be held solidarily liable with sellers upon clear showing of fault or negligence, including when they:

- a. Knowingly allow the sale of illicit health products;
- b. Fail to act after receiving FDA notice;

- c. Profit from the continued availability of violative listings;
- d. Systematically fail to implement reasonable compliance safeguards.

This Section shall be deemed a supplement to, and shall strengthen, the liability framework under Republic Act No. 11967 with respect to online transactions involving health products.

SECTION 9. Prohibited Acts. - It shall be unlawful to:

- a. Offer or sell FDA-regulated health products online without valid authorization from the Food and Drug Administration (FDA), including the appropriate License to Operate (LTO), Certificate of Product Registration (CPR), Certificate of Medical Device Registration (CMDR), or such other authorization as may be required under existing laws, rules, and regulations;
- b. Advertise health products with false, misleading, or unapproved claims;
- c. Circumvent FDA monitoring or takedown orders;
- d. Facilitate anonymous or untraceable sales of health products;
- e. Obstruct FDA inspections or investigations.

SECTION 10. Penalties. -

A. Digital Platforms. -

- i. Fine of ₱500,000 to ₱10,000,000 per violation depending on gravity, frequency, and public health impact;
- ii. Suspension or restriction of platform operations involving health products;
- iii. Recommendation for ISP or app store delisting, subject to applicable laws.

B. Sellers. -

- i. Fine of ₱100,000 to ₱5,000,000, per violation depending on gravity, frequency, and public health impact;
- ii. License revocation;
- iii. Criminal prosecution under Republic Act No. 9711 and related laws.

Each violative listing may be treated as a separate offense, subject to the discretion of the FDA based on the circumstances of the case.

SECTION 11. Relationship with Republic Act No. 11967 (Internet Transactions Act). - This Act shall be construed as a special law that supplements and strengthens Republic Act No. 11967 with respect to online transactions involving FDA-regulated health products.

In case of conflict, the provisions of this Act and Republic Act No. 9711 shall prevail with respect to online transactions involving health products.

SECTION 12. Implementing Rules and Regulations. - Within ninety (90) days from the effectivity of this Act, the FDA, in coordination with the DTI, DICT, NTC, and other relevant agencies, shall promulgate the necessary rules and regulations for the effective implementation of this Act.

SECTION 13. Separability Clause. - If any provision of this Act is declared unconstitutional or invalid, the remaining provisions shall not be affected thereby.

SECTION 14. Repealing Clause. - All laws, decrees, executive orders, rules and regulations, or parts thereof inconsistent with this Act are hereby repealed or modified accordingly.

SECTION 15. Effectivity Clause. - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation.

Approved,