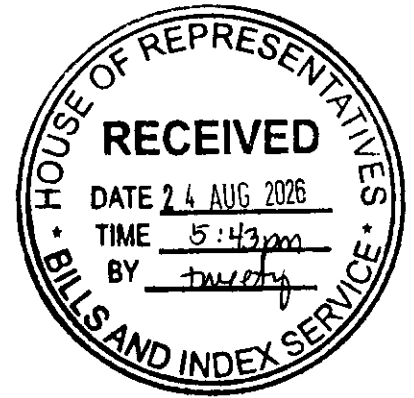


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

TWENTIETH CONGRESS
Second Regular Session

HOUSE BILL NO. **10922**



Introduced by **Representative ELMER V. CATULPOS**
(Ibrahim Party-List)

EXPLANATORY NOTE

Somewhere tonight, a father is cutting his maintenance tablets in half — not because his doctor told him to, but because the price of the branded medicine leaves no other arithmetic, and the cheaper generic that would save him is not yet on the shelf. It exists. It has been proven safe, sometimes by the strictest regulators on earth. It is simply waiting — sa pila, in a queue inside a government office, where an application can sit for months or years while the family it would have helped ration its own health. Ang gamot na naantala ay gamot na ipinagkait.

The size of that queue is now a matter of public record. In April 2026, at the first Joint Congressional ARTA-FDA Stakeholders Forum — convened in line with the President's own directive to streamline all government processes — lawmakers, regulators, and industry counted *more than 18,000 applications pending* before the Food and Drug Administration, a backlog that stakeholders warned was endangering patient access to life-saving medicines. Every application in that number is a cheaper generic absent from a drugstore shelf, a Filipino-made product that cannot launch, a small manufacturer paying rent on a factory that cannot sell, and a price that stays high because its competitor is stuck in line.

Let this Chamber be exact about where the fault lies, because it does not lie with the men and women of the FDA. Hindi masamang ahensya ang FDA; kulang ito sa tao, sa laboratoryo, sa sistema, at sa panahon. The agency regulates one of the widest product universes in government — every medicine, food, cosmetic, and device sold to one hundred ten million Filipinos — with fewer than a thousand personnel, and with core processes that, until this very year, were still filed on paper. Its evaluators did not choose the queue. They inherited it — and the proof is that the queue keeps returning no matter who leads. In 2021, a Director General ordered a one-time clearing of a backlog then counted at some *eighty thousand (80,000)* applications, accumulated over nearly a decade. It was cleared — and it grew back. Ang backlog na nililinis tuwing may bagong pinuno ay hindi problema ng pinuno. Problema ito ng sistema — at ang sistema ay maaayos lamang ng batas.

This Representation therefore begins with gratitude, because the FDA's present leadership has already begun the repair. The Director General's reform program has made access its guiding principle — strengthening human resources, digitalizing regulatory systems, expanding reliance pathways, and reinforcing enforcement. The agency has begun moving the manual filings of its drug regulation center online. And years earlier, the FDA itself pioneered the boldest accelerator in its toolbox: circulars establishing abridged and verification review, under which a drug already approved by stringent foreign regulators may be registered here on the strength of work already done to the highest standard. These reforms deserve more than praise. They deserve permanence. For a circular can be revised by any future administration, an initiative ends with its author's term, and a reform that lives on the goodwill of incumbents is a reform the next backlog can outlast. Ang mabuting palakad ay dapat maging batas, upang hindi na ito matapos sa paglipas ng panunungkulan.

What, then, does this bill do? It writes the repairs into statute and adds what only statute can add. First, risk-based regulation: applications classified by risk, so that the FDA's finite scientists concentrate on what genuinely threatens public health — and on the counterfeit and substandard products that do — while renewals, minor variations, and products already proven abroad move through simplified lanes. Second, enforceable deadlines with teeth: every application decided within fixed periods, and a low-risk application left undecided beyond its period is deemed approved by operation of law, without prejudice to post-market surveillance — because a deadline without consequence is a suggestion. Third, the reliance pathways given permanent statutory footing and extended beyond new drugs to the renewals and generics that fill ordinary Filipinos' prescriptions. Fourth, a time-bound program to clear the existing backlog — and, for the first time, a permanent early-warning mechanism so that no backlog may ever again accumulate silently for a decade before anyone is required to answer for it. Fifth, a fully digital FDA, end to end, with every applicant seeing the status of their application in real time. And sixth, the laboratories, equipment, and evaluator corps the agency should have been given long ago.

Let one thing be beyond misunderstanding, because it will be the first attack: faster is not weaker. This measure does not lower a single standard of safety, efficacy, or quality. It does not touch the FDA's power to refuse, suspend, or recall any product on public-health grounds — it reinforces that power by freeing the agency's experts from re-checking what the world's strictest regulators have already checked, so they may guard instead against what actually kills: the counterfeit, the substandard, the unregistered. Ang bilis ay hindi kabawasan ng ingat. Ito ay ingat na inilagay, sa wakas, sa tamang panganib.

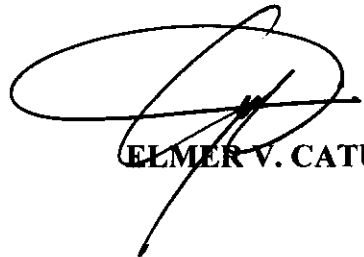
This Representation must also speak with candor. The author of this bill is engaged in pharmaceutical distribution and pharmacy retail, and has stood on the applicant's side of this queue. That experience is disclosed plainly, and it teaches something worth the Chamber's attention: the queue burdens every applicant, large and small alike — but it does not burden them equally. The large firm can wait out a two-year registration; the small Filipino

manufacturer often cannot, and the patient never can. The first beneficiaries of a faster FDA are not the established players, who have learned to live with the delay and whose incumbency the delay quietly protects. They are the challenger, the start-up, the generics maker whose cheaper product the queue keeps off the market — and the father who is cutting his tablets in half while it waits. Ang pinakamalaking kalaban ng mahal na gamot ay ang murang gamot na nakapila.

This measure is one half of a pair that this Representation brings before this Congress. Its companion, the Abot-Gamot Act, extends the pharmacist's supervised reach to every barangay, so that genuine medicines arrive where Filipinos actually live. This bill answers the other end of the same journey: that the medicine enters the market without needless delay. Bilis sa itaas, abot sa ibaba — iisang layunin, ang tunay at abot-kayang gamot sa kamay ng bawat Pilipino.

The measure honors the legislative review of the FDA charter already begun by the Committees on Revision of Laws and on Health, and is drafted to complement, never to compete with, that effort: it stays deliberately silent on questions of the agency's structure and placement, and confines itself to the outcomes ordinary Filipinos feel — speed, access, and safety delivered together. Its provisions are drafted to stand alone and to dock, intact, into any strengthened FDA charter this Congress may enact. *SONA anchor: check the archive for an unused passage on medicines, health access, or streamlining before filing — one-unique-quote rule.*

Every month this measure waits, another cohort of applications joins the queue, another cohort of prices stays high, and another month of tablets is cut in half at kitchen tables across the Republic. In view of the foregoing, the approval of this Bill is earnestly requested.



ELMER V. CATULPOS

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

TWENTIETH CONGRESS
Second Regular Session

HOUSE BILL NO. 10922

*Introduced by **Representative ELMER V. CATULPOS***
(I Tahanan Party-list)

**AN ACT MODERNIZING THE FOOD AND DRUG ADMINISTRATION BY
IMPOSING ENFORCEABLE PROCESSING TIMELINES WITH AUTOMATIC
APPROVAL FOR LOW-RISK APPLICATIONS, GIVING PERMANENT
STATUTORY FOOTING TO THE REGULATORY RELIANCE PATHWAYS,
ELIMINATING THE APPLICATION BACKLOG AND PREVENTING ITS
RECURRENCE, MANDATING FULL DIGITALIZATION, STRENGTHENING
TESTING AND HUMAN RESOURCE CAPACITY, AMENDING FOR THE
PURPOSE PERTINENT PROVISIONS OF REPUBLIC ACT NO. 9711,
AND APPROPRIATING FUNDS THEREFOR**

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

ARTICLE I — GENERAL PROVISIONS

Section 1. Short Title. — This Act shall be known and cited as the “Bilis-Gamot Act,” or the “FDA Modernization and Backlog Elimination Act of 2026.”

Section 2. Declaration of Policy. — It is the policy of the State to protect and promote the right to health of the Filipino people by ensuring the safety, efficacy, and quality of health products — and to guarantee that this protection is delivered without needless delay, for a protection delayed is, to the patient who waits, a protection denied. The State declares that the regulation of health products shall be risk-based, concentrating scientific scrutiny where risk to public health is greatest; that the Food and Drug Administration (FDA) shall decide within firm and enforceable timelines; that reliance upon the completed evaluations of stringent regulatory authorities is sound regulatory science and shall have permanent statutory footing; that the FDA shall be equipped with the personnel, laboratories, and digital systems its mandate requires; and that no provision of this Act shall be construed to diminish any standard of safety, efficacy, or quality, or any power of the FDA to refuse, suspend, or recall any product in the interest of public health.

Section 3. Objectives. — This Act shall have the following objectives:

- (a) To institute risk-based classification and processing of all applications before the FDA;

- (b) To impose enforceable processing timelines, with approval by operation of law for low-risk applications left undecided beyond their periods;
- (c) To give permanent statutory footing to the regulatory reliance pathways pioneered by the FDA, and to extend them to renewals, variations, and generic medicines;
- (d) To eliminate the existing application backlog within a fixed period, and to establish a permanent mechanism preventing its silent recurrence;
- (e) To complete the end-to-end digitalization of the FDA's regulatory processes;
- (f) To strengthen the FDA's laboratories, equipment, and human resource complement; and
- (g) To lower the price and hasten the availability of quality medicines, particularly generics and essential medicines, for the Filipino people.

Section 4. Definition of Terms. — As used in this Act:

- (a) **Health Product** refers to food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostics, household/urban hazardous substances, and such other products regulated by the FDA under Republic Act No. 9711 and Republic Act No. 3720, as amended;
- (b) **Marketing Authorization** refers to the certificate of product registration, license to operate, or other authorization required before a Health Product may be manufactured, imported, distributed, or sold;
- (c) **Stringent Regulatory Authority** refers to a foreign or international regulator of recognized rigor, including World Health Organization-Listed Authorities and such comparable authorities as the FDA shall list;
- (d) **Regulatory Reliance** refers to the FDA's use of, or reliance upon, the assessments, inspections, or approvals of a Stringent Regulatory Authority in reaching its own decision, without abdicating its final regulatory authority, including the abridged and verification review pathways;
- (e) **Low-Risk Application** refers to an application so classified under Section 5, including renewals, minor variations, and applications for products previously approved by a Stringent Regulatory Authority;
- (f) **Automatic Approval** refers to approval by operation of law under Section 6;
- (g) **Backlog** refers to all applications pending beyond their prescribed processing periods.

ARTICLE II — SPEED WITH SAFETY

Section 5. Risk-Based Classification. — The FDA shall classify all applications for Marketing Authorization by risk, distinguishing Low-Risk Applications from applications requiring full scientific evaluation, and shall publish the classification standards. The FDA's scientific resources shall be concentrated on high-risk evaluation and on post-market surveillance and enforcement against counterfeit, substandard, and unregistered products, while Low-Risk Applications proceed through simplified and expedited lanes. Nothing in the classification shall exempt any product from the standards of safety, efficacy, and quality under existing law.

Section 6. Enforceable Timelines; Automatic Approval. — The FDA shall decide every application within maximum processing periods fixed in the implementing rules, consistent with and not exceeding those allowed under Republic Act No. 11032. Upon the lapse of the prescribed period for a Low-Risk Application without final action, the application shall be deemed approved by operation of law, and the corresponding authorization shall be generated and released to the applicant without further request — without prejudice to post-market surveillance, to the FDA's power to suspend or recall, and to the administrative liability of any

officer responsible for the inaction. For applications requiring full evaluation, any extension shall be in writing, stating its scientific ground and a definite date of decision, which shall be binding.

Section 7. Permanent Statutory Footing of Regulatory Reliance. — The regulatory reliance pathways pioneered by the FDA — including abridged review and verification review for products previously approved by Stringent Regulatory Authorities — are hereby adopted, given the force of law, and made permanent, and the FDA's issuances establishing them shall continue in effect as the implementing detail of this Section, as the FDA may update them consistently herewith. The FDA shall extend the reliance pathways, under standards it shall fix, to renewals, minor variations, and applications for generic medicines whose reference products or foreign equivalents have been approved by Stringent Regulatory Authorities. The FDA shall publish and periodically update the list of recognized Stringent Regulatory Authorities. No reliance pathway shall diminish the FDA's authority to require local labeling and pharmacovigilance, or to refuse, suspend, or recall any product on public-health grounds.

Section 8. Priority Lane for Essential and Generic Medicines. — Applications for generic medicines and for medicines in the Philippine National Formulary or the national list of essential medicines shall be afforded priority processing, that the medicines most needed and most affordable to Filipinos shall never wait behind products of lesser public-health consequence. The FDA shall report the median processing time of this lane under Section 18.

Section 9. Integrity of Standards. — Nothing in this Act shall be construed to lower any standard of safety, efficacy, or quality; to limit the FDA's police power, inspection, and enforcement functions; or to restrain the FDA from refusing, suspending, or recalling any product, or from requiring any additional evidence, where public health so requires, with the reasons stated in writing.

ARTICLE III — THE BACKLOG: ELIMINATION AND PREVENTION

Section 10. Backlog Elimination Program. — Within thirty (30) days from the effectivity of this Act, the FDA shall establish a time-bound Backlog Elimination Program to decide all backlogged applications within a period not exceeding eighteen (18) months. For this purpose, the FDA may engage additional qualified evaluators on a term basis, deputize accredited independent experts subject to strict conflict-of-interest safeguards, and apply the reliance pathways under Section 7 and the risk classification under Section 5. Applications cleared under the Program remain subject to post-market surveillance.

Section 11. Monthly Public Reporting. — During the Program, the FDA shall publish monthly the number of backlogged applications remaining by category, the number decided, and the average processing times, that the public and the Congress may follow the clearing of the queue in the open.

Section 12. Never Again: The Backlog Early-Warning Mechanism. — To prevent the silent recurrence of any backlog, the FDA shall monitor continuously the number of applications pending beyond their prescribed periods. Whenever such number exceeds the threshold fixed in the implementing rules for any center or category during two (2) consecutive quarters, the FDA shall, without need of demand: (a) report the fact, its causes, and a time-bound catch-up plan to the Secretary of Health and to both Houses of Congress; and (b) publish the same on

the dashboard under Section 18. The Republic has cleared its medicine queues before, only to watch them silently return; henceforth, no backlog shall be permitted to accumulate for years unseen and unanswered.

ARTICLE IV — THE DIGITAL FDA

Section 13. End-to-End Electronic Processing. — The FDA shall operate a fully electronic, end-to-end system for the filing, payment, tracking, evaluation, and issuance of all authorizations across all its centers — including the registration of drugs and over-the-counter medicines — with the real-time status of every application visible to the applicant. Manual filing shall be retired under a transition schedule fixed in the implementing rules, with assisted filing maintained for micro and small applicants.

Section 14. Interoperability. — The FDA's electronic systems shall be interoperable with the systems of the Bureau of Customs, the Department of Trade and Industry, the Bureau of Internal Revenue, and local government units, to eliminate redundant submissions, consistent with Republic Act No. 11032 and Republic Act No. 10173; and with any national medicines traceability system established by law, so that the record of a product's registration and the record of its journey to the patient shall speak to each other, and the counterfeit shall find no gap between them.

ARTICLE V — CAPACITY

Section 15. Laboratories and Equipment. — The State shall invest in the modernization of the FDA's testing laboratories and equipment, building upon Republic Act No. 9711, and the FDA shall pursue international laboratory accreditation and mutual recognition arrangements in support of the reliance pathways.

Section 16. Human Resource Complement. — The FDA, with the Department of Budget and Management and the Civil Service Commission, shall augment its evaluator corps and technical personnel commensurate to its mandate, and shall implement retention and development programs — including training, specialization tracks, and competitive compensation within existing authority — that the Republic may keep the scientists it trains. The FDA shall report annually its staffing complement against its application volume.

Section 17. Fees and Retention of Income. — The FDA may adjust its fees and charges to reasonable, cost-based levels, and shall retain and apply its income consistent with Republic Act No. 9711 to carry out this Act, particularly the engagement of evaluators, the digital systems, and the laboratory program. Fee adjustments shall never be used to ration, deter, or delay applications, and simplified fees shall be maintained for micro and small enterprises.

ARTICLE VI — TRANSPARENCY AND ACCOUNTABILITY

Section 18. The Bilis-Gamot Dashboard. — The FDA shall maintain a publicly accessible online dashboard showing, at minimum: pending applications by center and category; average, median, and longest processing times; the status of the Backlog Elimination Program and thereafter of the early-warning mechanism; the median processing time of the priority lane

under Section 8; and the list of recognized Stringent Regulatory Authorities — updated at intervals fixed in the implementing rules, that the performance of the Republic's health-product regulator may be seen by all.

Section 19. ARTA Oversight. — The Anti-Red Tape Authority shall monitor the FDA's compliance with the timelines and automatic-approval requirements of this Act and of Republic Act No. 11032, and shall include the FDA in its regular public reporting.

Section 20. Annual Report and Congressional Oversight. — The FDA shall submit to both Houses of Congress an annual report on the implementation of this Act. A Congressional Oversight Committee, composed of the chairpersons and members of the appropriate committees of both Houses, shall review the effectiveness of this Act — particularly the elimination and non-recurrence of the backlog, processing times, and the availability and prices of generic and essential medicines — within three (3) years from its effectivity.

ARTICLE VII — FINAL PROVISIONS

Section 21. Appropriations. — The amount necessary for the initial implementation of this Act, particularly the Backlog Elimination Program, the digital systems, and the laboratory and personnel programs, shall be charged against the current appropriations of the FDA and the Department of Health, augmented by an initial appropriation of *One Billion Pesos (P1,000,000,000.00)* as a distinct line item supplementary to the income retained by the FDA and not sourced by diminishing existing health programs. Thereafter, the amounts necessary shall be included in the annual General Appropriations Act.

Section 22. Implementing Rules and Regulations. — The FDA, with the Department of Health, the Anti-Red Tape Authority, the Department of Information and Communications Technology, and in consultation with industry, professional, and consumer stakeholders, shall promulgate the implementing rules and regulations of this Act within ninety (90) days from its effectivity, including the processing periods, the risk-classification standards, the backlog threshold under Section 12, and the reliance procedures. Failure to promulgate the rules shall not prevent the implementation of the self-executing provisions of this Act.

Section 23. Relationship to Other Laws and Pending Legislation. — This Act amends and supplements Republic Act No. 9711 and Republic Act No. 3720, as amended, and shall be implemented in harmony with Republic Act No. 11032, Republic Act No. 11223, Republic Act No. 9502, and Republic Act No. 6675. In the event of the enactment of any law strengthening or amending the FDA charter, the provisions of this Act shall be deemed integrated therein and shall continue in full force, unless expressly repealed with specific reference to this Act. This Act shall likewise be construed together with its companion measure on pharmaceutical care access, with which it shares one object: the genuine, safe, and affordable medicine in the hand of every Filipino.

Section 24. Separability Clause. — If any provision or part of this Act is declared invalid or unconstitutional, the remaining provisions or parts not affected shall remain in full force and effect.

Section 25. Repealing Clause. — All laws, decrees, orders, rules and regulations, or parts thereof inconsistent with this Act are hereby repealed or modified accordingly.

Section 26. Effectivity. — This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation.

Approved,