EXECUTIVE ORDER

ELIMINATING BARRIERS TO AFFORDABLE INSULIN

A Market-Based Plan to Deliver Safe, Affordable Insulin Without New Spending

This Order accelerates access to FDA-verified, safe insulin by recognizing the identical, trusted work already performed by our closest allies. We are cutting redundant review, not safety corners.

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1: POLICY AND PURPOSE

Approximately 8 million Americans require daily insulin to survive. The average U.S. insulin price exceeds $300 per vial—ten to forty times the price in allied nations with equivalent safety standards. Americans are rationing insulin and dying from preventable complications because regulatory redundancy blocks FDA-verified alternatives from reaching U.S. pharmacies.

No American should die because outdated processes make a century-old medicine artificially expensive.

The European Medicines Agency, United Kingdom Medicines and Healthcare products Regulatory Agency, and Japan's Pharmaceuticals and Medical Devices Agency maintain safety and efficacy standards equivalent to FDA's, use identical international protocols (ICH guidelines), and review the same multinational clinical trial data. **Requiring FDA to fully re-review identical safety data already affirmed by recognized foreign agencies undermines the FDA's core mission of patient safety by forcing duplication that wastes finite regulatory resources. The FDA's primary safety duty is best discharged through enhanced post-market surveillance rather than redundant pre-market review.**

This Order is not about importation—it is about acceleration. This Order leverages the full scope of authority under 42 U.S.C. §262(k) (Biosimilarity) and 21 U.S.C. §356c (Shortage Management) to ensure market competition delivers FDA-verified insulin to Americans who need it. This is a policy of regulatory acceleration and reliance, not drug importation. Bureaucratic inertia shall not substitute for judgment, and process shall not obstruct outcomes.

This Order is premised on removing barriers to competition, not creating new government programs. It requires zero new taxpayer spending and is projected to save federal programs $4-5 billion annually. Success will be measured by patient access and market impact, not by process completion.

SECTION 2: IMMEDIATE DIRECTIVES TO FDA

To the maximum extent permitted by law and consistent with available appropriations, the Commissioner of Food and Drugs shall take the following actions:

(a) PRIORITY INSULIN IDENTIFICATION

Within **10 days** of the date of this order, publish a list of 2-5 specific insulin products currently approved by EMA, MHRA, or PMDA that:

(i) Address common insulin needs (human regular, NPH, and/or rapid-acting or long-acting analogs);

(ii) Are manufactured by entities with established GMP compliance records and current FDA registration or eligibility for registration;

(iii) Have manufacturers prepared to file Biologics License Applications (BLAs) or applications under 42 U.S.C. § 262(k) for the U.S. market;

(iv) Are manufactured with sufficient global production capacity to avoid supply disruption in other markets; and

(v) May be designated shortage-sensitive under 21 U.S.C. § 356c based on documented supply constraints or public health need as determined by FDA shortage databases, ASHP Drug Shortages Database, or similar authoritative sources.

The Commissioner shall, within the same publication, issue a formal communication to each identified manufacturer confirming the Administration's intent to maintain this policy direction under existing statutory authority and inviting submission of streamlined applications.

(b) STREAMLINED RELIANCE PATHWAY GUIDANCE

Within **30 days** of the date of this order, issue interim final guidance under 42 U.S.C. § 262(k) and related authorities establishing a reliance-based review process for insulin products approved by recognized foreign agencies, including:

(i) Model dossier outline (maximum 10 pages) specifying required documentation for applications relying on foreign assessments;

(ii) **Regulatory reliance framework** permitting acceptance of foreign agency assessments for chemistry, manufacturing, controls, and nonclinical/clinical data where the foreign agency applied ICH-harmonized standards;

(iii) Acceptance of foreign GMP inspections conducted under the U.S.-EU Mutual Recognition Agreement (MRA), U.S.-UK MRA, or equivalent arrangements, with FDA retaining authority to conduct for-cause inspections;

(iv) Streamlined registration requirements limited to: verification of foreign approval status; English labeling compliance; Drug Supply Chain Security Act (DSCSA) serialization and tracking documentation pursuant to 21 U.S.C. § 360eee-1; Good Distribution Practice (GDP) certification; temperature validation records; and commitment to FDA adverse event reporting systems (FAERS/Sentinel);

(v) Clear pathways for manufacturers to demonstrate biosimilarity or interchangeability under § 262(k), leveraging foreign approval data where scientifically appropriate.

Critical Legal Foundation: All actions under this subsection shall be implemented as interpretations and applications of existing statutory authorities under the Public Health Service Act and Federal Food, Drug, and Cosmetic Act. This guidance establishes **regulatory reliance, not regulatory compromise**—FDA retains full authority over safety determinations while eliminating duplicative review of data already assessed by agencies using equivalent standards. **This guidance does not alter evidentiary standards under 42 U.S.C. § 262(k) or create new approval standards; it clarifies how existing authorities may be exercised efficiently when foreign assessments under ICH-harmonized protocols are available.**

Budget-Neutral Implementation: All activities under this Order shall be executed as reallocation of existing FDA resources and user fees collected under the Biosimilar User Fee Act (BsUFA II, III, and IV, 42 U.S.C. § 262 note). The Commissioner shall treat streamlined pathway reviews as priority BsUFA activities within the scope of BsUFA authorities for biosimilars and consistent with the BsUFA commitment letter, ensuring implementation proceeds without requiring new appropriations and remains insulated from appropriations riders. Fee-funded resources shall be used consistent with statutory BsUFA purposes. No new taxpayer funding is required or authorized by this Order.

BsUFA Resourcing and Staffing Flexibility: The Commissioner is authorized to temporarily reallocate BsUFA-funded staff to the dedicated insulin review team and to accept surge detailees from other FDA divisions to meet processing demands. Current staffing levels for the insulin review team shall be published on the Public Milestone Tracker and updated monthly.

This interim final guidance shall be issued under the "good cause" exemption to notice-and-comment rulemaking (5 U.S.C. § 553(b)(B)), with subsequent notice-and-comment period initiated within 90 days to ensure public participation while addressing immediate public health need.

(c) RAPID INTAKE PROCESS

Within **30 days** of the date of this order, establish and publish:

(i) Dedicated review team with clear authority and cross-functional expertise;

(ii) **Service Level Commitment** of 10-15 business days for complete applications submitted under the streamlined reliance pathway. The Service Level Commitment is an internal management performance standard established to ensure timely execution. It creates no enforceable right or obligation under the Administrative Procedure Act or any other law. If FDA does not meet this commitment, it must publish a variance memorandum within 48 hours explaining the delay, identifying corrective actions, and providing a revised completion date. The Commissioner shall schedule a corrective action review for any missed commitment;

(iii) Weekly public metrics showing applications received, applications determined complete, applications under review, and applications resolved (approved, licensed, refused, or requiring additional information);

(iv) Clear completeness criteria and review standards provided to applicants within 5 business days of submission, with specific guidance on what constitutes acceptable foreign assessment documentation.

Definition of Complete Application: FDA shall publish a "Definition of Complete Application" document specifying all required elements for a streamlined reliance pathway application. FDA should issue completeness determinations within 5 business days of submission. For internal scheduling and performance metrics purposes, applications not receiving a deficiency notification within 5 business days shall be treated as complete, though this provision does not create any third-party rights or obligations.

(d) ENFORCEMENT DISCRETION FOR PUBLIC HEALTH NEEDS

Within **60 days** of the date of this order, and to the maximum extent permitted by law, including authority under 21 U.S.C. § 356c (drug shortage response):

(i) Exercise enforcement discretion to facilitate priority review under § 262(k) with targeted enforcement discretion and enhanced post-market conditions for priority insulin products in shortage-sensitive contexts. **For purposes of this section, a shortage-sensitive context shall be determined based on:**

- **Documented domestic supply constraints** in FDA drug shortage databases, ASHP Drug Shortages Database, or manufacturer shortage notifications;
- **Public health need determinations** based on significant documented patient rationing or access barriers, supported by evidence from clinician surveys, emergency department data, endocrinology practice reports, or patient advocacy organizations; or
- **Supply chain vulnerability assessments** indicating insufficient domestic manufacturing redundancy.

Supporting consideration (non-determinative): Evidence of severe price disparity compared to median international reference prices may inform public health impact assessments but shall not serve as the sole or primary basis for shortage-sensitive determinations.

Nothing herein authorizes distribution of any insulin product absent an effective Biologics License Application under 42 U.S.C. § 351 or lawful exercise of enforcement

discretion within FDA's existing statutory authorities. Section 356c supports prioritization and targeted enforcement discretion but does not create independent market authorization authority.

(ii) Announce time-boxed windows (6-12 months, renewable based on market conditions) during which such discretion will be available, with clear criteria for renewal or termination;

(iii) Require enhanced post-market surveillance, adverse event reporting, and quarterly safety reviews as conditions of accelerated entry;

(iv) Ensure all products entering under enforcement discretion comply fully with DSCSA serialization requirements pursuant to 21 U.S.C. § 360eee-1, GDP standards, and cold-chain integrity verification.

This framework leverages FDA's existing shortage-response authority, not importation authority under 21 U.S.C. § 384 or § 804 (which exclude biologics). All insulin products entering the U.S. market under this Order must be submitted by FDA-registered manufacturers or authorized BLA/351(k) applicants—not third-party distributors or parallel traders.

(e) ELIMINATION OF DUPLICATIVE REQUIREMENTS

To the maximum extent permitted by law, and consistent with maintaining safety standards, streamline requirements by:

(i) Accepting clinical trial data and manufacturing documentation already reviewed by recognized foreign agencies applying ICH-harmonized standards, rather than requiring complete resubmission and independent re-review;

(ii) Eliminating requirements for additional clinical studies for products substantially similar to those already approved abroad by agencies using equivalent review standards;

(iii) Prioritizing abbreviated pathways under § 262(k) where appropriate, rather than requiring full standalone BLA applications;

(iv) Accepting MRA-covered foreign facility inspections as presumptive evidence of GMP compliance subject to risk-based verification, with FDA retaining authority to conduct for-cause inspections based on specific safety signals or risk assessments.

FDA reviewers shall document any instance where duplication is retained in excess of the streamlined pathway standards, including a specific justification identifying the concrete safety rationale or legal requirement that necessitates additional review. Such documentation must be approved by the review team lead and shall be included in weekly progress reports to ensure accountability and continuous improvement. **Generalized concerns about "foreign manufacturing" or "unfamiliarity with foreign data" shall not constitute adequate justification for duplicative review.**

Nothing in this subsection shall be construed to create a new approval standard or diminish FDA's safety authority. FDA retains full discretion to require additional

information, conduct inspections, or apply traditional review processes where specific, articulable safety concerns warrant.

(f) ACCOUNTABILITY AND REGULATORY EFFICIENCY

Delays attributable solely to internal administrative processes—rather than legitimate safety or legal concerns—are inconsistent with this directive to execute laws efficiently. The Commissioner shall prioritize patient impact and science-based regulatory efficiency over procedural redundancy.

Nothing in this section limits FDA's authority to inspect facilities, require additional data, suspend approvals, or take enforcement action based on safety concerns. **This is acceleration, not corner-cutting.**

SECTION 3: TRANSPARENCY AND MARKET ACTIVATION

To the maximum extent permitted by law and consistent with available appropriations:

(a) PRICE TRANSPARENCY DASHBOARD

Within **30 days** of the date of this order, the Administrator of CMS shall launch a public dashboard displaying:

(i) Quarterly insulin prices: U.S. vs. UK, Germany, France, Japan, Canada;

(ii) Median international reference prices;

(iii) Price disparities by product and manufacturer;

(iv) Accessible charts, tables, and downloadable data.

All data shall be published in machine-readable format (JSON, CSV) to ensure public accessibility and enable third-party analysis. The dashboard shall prominently display explanatory context clarifying that international price data is presented for transparency purposes and does not constitute regulatory price controls. **The dashboard shall include a note that estimates reflect competition-driven price changes resulting from increased market entry; this initiative employs no price controls.**

(b) PATIENT TOOLS

Within **45 days** of the date of this order, the Secretary of HHS shall publish:

(i) Cash-price pharmacy locator showing where newly available FDA-verified insulin products are stocked;

(ii) Plain-language patient guides explaining product options, how to report adverse events, and available financial assistance programs;

(iii) Provider one-pagers with product mapping, dose equivalence guidance, and patient counseling protocols.

All materials shall emphasize that newly available products have been approved through FDA's streamlined reliance pathway and remain subject to full FDA safety oversight.

(c) SUBSTITUTION GUIDANCE

Within **15 days** of the date of this order, the Commissioner shall issue interim final guidance clarifying that pharmacists may substitute insulin products of the same type and interchangeability designation where permitted by state pharmacy law, and publish an insulin product mapping table categorizing products by type, class, and interchangeability status to assist state boards of pharmacy in updating substitution rules.

This guidance shall explicitly address compliance requirements under the Drug Supply Chain Security Act (21 U.S.C. § 360eee-1 et seq.) for products entering through the streamlined pathway, affirming that only DSCSA-compliant serialization and track-and-trace documentation will be accepted. The guidance shall provide clear standards for pharmacist verification of product authenticity and supply chain integrity.

Pharmacist Professional Practice Clarification: The guidance shall clarify that pharmacists who substitute insulin products approved or licensed under the streamlined reliance pathway, acting in accordance with state pharmacy law and in compliance with DSCSA serialization and cold-chain integrity protocols, are exercising appropriate professional judgment. Such pharmacists are dispensing FDA-verified products through documented, compliant supply chains and should not face additional professional liability concerns beyond those applicable to any insulin product substitution permitted under state law. **This clarification is consistent with state law and does not preempt state professional standards.** This guidance is intended to support pharmacist confidence in stocking and dispensing newly approved products, ensuring patient access is not impeded by unfounded liability concerns.

(d) FEDERAL FACILITY LEADERSHIP

Within **45 days** of the date of this order, the Secretary shall:

(i) Encourage VA, IHS, DoD, and 340B covered entities to evaluate priority insulin products approved under the streamlined pathway for formulary inclusion;

(ii) Publish federal acquisition guidance addressing procurement, formulary review, and utilization management for newly approved insulin products.

Within **60 days**, the Secretary shall coordinate with major pharmacy chains to identify and publicize pilot locations stocking newly approved insulin products, with special attention to underserved and high-need communities.

(e) PAYER GUIDANCE

Within **45 days** of the date of this order, the CMS Administrator shall issue non-binding guidance encouraging Medicare Advantage and Part D plans, Medicaid managed care organizations, and commercial insurers to:

(i) Provide formulary tier parity for lower-priced insulin products approved under the streamlined pathway;

(ii) Streamline or eliminate prior authorization for these products;

(iii) Proactively communicate lower-cost options to beneficiaries at point of prescription.

Within the same period, CMS shall publish and maintain a voluntary registry of participating plans or PBMs that have implemented parity provisions, reduced cost-sharing, or zero-copay tiers for newly approved insulin products.

SECTION 4: POST-MARKET SAFETY AND PHARMACOVIGILANCE

All insulin products entering through streamlined pathways remain subject to full FDA post-market surveillance and enforcement authority. There is no compromise on safety—only on duplicative process.

The Commissioner shall:

(a) Enhanced Monitoring for New Entrants

Establish enhanced pharmacovigilance protocols for newly approved products during the first 12 months post-launch, including:

(i) Active surveillance through FDA's Sentinel System;

(ii) Mandatory manufacturer reporting on supply chain integrity, cold-chain compliance, and distribution patterns;

(iii) Expedited review of adverse event reports (AERs) submitted through FAERS.

(b) Transparent Safety Reporting

Publish **quarterly public safety reports** comparing adverse event rates, manufacturing quality metrics, and supply chain compliance for products approved under the streamlined pathway versus traditionally approved products. Reports shall be accessible, data-driven, and designed to build public confidence in regulatory reliance frameworks.

(c) Full Enforcement Authority Retained

FDA retains unrestricted authority to:

(i) Immediately suspend or revoke approval for any product based on safety signals or quality concerns;

(ii) Conduct for-cause facility inspections regardless of MRA coverage;

(iii) Require labeling changes, Risk Evaluation and Mitigation Strategies (REMS), or additional post-market studies;

(iv) Take any enforcement action authorized under the Federal Food, Drug, and Cosmetic Act or Public Health Service Act.

Nothing in this Order limits FDA's enforcement authority or compromises safety standards. Regulatory efficiency does not mean regulatory abdication.

SECTION 5: COORDINATION AND OVERSIGHT

(a) IMPLEMENTATION COORDINATOR

The Secretary of HHS shall designate a single **Implementation Coordinator** accountable for cross-agency execution, obstacle resolution, and weekly progress reports to the White House Domestic Policy Council. The Coordinator shall have authority to convene interagency meetings and propose solutions to maintain implementation timelines.

The Coordinator shall have direct authority to escalate delays attributable to administrative processes (including "awaiting clearance," "data harmonization pending," "legal review in progress," or similar procedural holds) to agency heads and the White House for immediate resolution.

Escalation Protocol:

- **5 business days beyond deadline:** Mandatory report to Implementation Coordinator with specific justification identifying the blocking office, division, or process stage.
- **10 business days beyond deadline:** Automatic Tier-2 escalation to Deputy Secretary/Commissioner level AND notification to the White House Domestic Policy Council. A brief public note shall be posted on the Public Milestone Tracker stating: delay reason, corrective action being taken, and revised estimated completion date.

Expedited Clearance Protocol: All internal clearances (legal, communications, Paperwork Reduction Act) shall operate under a 48-hour turnaround requirement, to the extent consistent with law and Executive Order 12866. Any office requiring more than 48 hours must provide written legal citation or specific safety rationale for the delay. Unresolved clearance delays exceeding 48 hours escalate automatically to the Implementation Coordinator for resolution.

(b) OMB REGULATORY REFORM DASHBOARD AND CAP GOAL DESIGNATION

Within **15 days** of the date of this order, the Director of the Office of Management and Budget shall:

(i) Add this insulin initiative to OMB's **Regulatory Reform Dashboard** with public tracking of all deadlines and deliverables specified in Section 8;

(ii) **Designate this initiative as a Cross-Agency Priority (CAP) Goal** under the Government Performance and Results Act (GPRA), requiring quarterly data-driven reviews modeled on Performance Management and Analysis (PMA/STAT) sessions, chaired by the White House Domestic Policy Council. **Quarterly CAP Goal reviews will publish action items and decisions within 48 hours of each session;**

(iii) Establish **cross-agency tracking protocols** to identify and resolve interagency dependencies, clearance bottlenecks, or coordination delays;

(iv) Publish dashboard data publicly at reginfo.gov with granular milestone tracking, including sub-deadlines for internal clearances (e.g., "Draft submitted to OGC," "Clearance received from OMB," "Final signature obtained");

(v) Flag any milestone at risk of missing its deadline at least 10 days in advance, with mandatory explanation and corrective action plan;

(vi) Require agencies to report **clock-stops** (pauses in review timelines), delay reasons, and corrective actions. Any clock-stop exceeding 3 business days must be accompanied by written justification approved by both the Review Team Lead and the Implementation Coordinator, and published on the dashboard.

Quarterly CAP Goal Reviews: The Domestic Policy Council shall conduct quarterly data-driven reviews examining application throughput, timeline adherence, obstacle resolution, and market impact. These reviews shall be performance-focused and action-oriented, with decisions documented and communicated to relevant agencies within 48 hours.

This dashboard and CAP Goal structure prevents long-tail administrative evasion by making procedural delays visible, accountable, and subject to regular executive scrutiny.

(c) PUBLIC MILESTONE TRACKER

Within **30 days** of the date of this order, HHS shall launch a **public milestone tracker** accessible at HHS.gov, showing real-time progress against each deadline in this Order, with brief explanations for any delays exceeding 5 business days. This tracker shall include:

(i) Status indicators (on track / at risk / delayed / complete) for each deliverable;

(ii) **The Public Milestone Tracker shall identify the senior accountable official (Commissioner, Deputy Commissioner, or Division Director level) by name and title. Subordinate program staff shall be listed by organizational unit only;**

(iii) Date of last status update;

(iv) For any delayed milestone: specific reason for delay, corrective actions taken, and revised completion date;

(v) **Staffing levels** assigned to the insulin review team and streamlined pathway processing;

(vi) **Clock-stops and variance memos**: Documentation of any review timeline pauses exceeding 3 business days, including justification and approval chain;

(vii) **Service Level Commitment variance memos**: Any instance where FDA exceeded the 10-15 day review commitment, including the published variance memorandum.

The tracker shall be updated weekly and shall complement (not duplicate) the OMB Regulatory Reform Dashboard established in Section 5(b).) For any delayed milestone: specific reason for delay, corrective actions taken, and revised completion date;

(v) **Staffing levels** assigned to the insulin review team and streamlined pathway processing;

(vi) **Clock-stops and variance memos**: Documentation of any review timeline pauses exceeding 3 business days, including justification and approval chain;

(vii) **Service Level Commitment variance memos**: Any instance where FDA exceeded the 10-15 day review commitment, including the published variance memorandum.

The tracker shall be updated weekly and shall complement (not duplicate) the OMB Regulatory Reform Dashboard established in Section 5(b).

(d) LEGAL AND COMPETITIVE NEUTRALITY MEMORANDUM

Within **45 days** of the date of this order, the HHS General Counsel, in consultation with the Department of Justice, shall prepare a **Competitive Neutrality & Statutory Compliance Memorandum** detailing:

(i) The specific statutory authorities underlying each component of this Order;

(ii) How the streamlined pathway maintains competitive neutrality between domestic and foreign manufacturers (all must meet equivalent standards);

(iii) Legal analysis demonstrating compliance with the Administrative Procedure Act, including justification for interim final guidance under the "good cause" exception;

(iv) Analysis of how this framework differs from and avoids the legal limitations of 21 U.S.C. §§ 384 and 804 (which exclude biologics and involve reimportation).

This memorandum shall be made publicly available and serve as the legal foundation for defending the Order against anticipated litigation.

Litigation Readiness: The HHS General Counsel and Department of Justice shall establish a **rapid-response litigation cell** prepared to defend this Order against legal challenges. All final guidance documents, FAQs, public metrics, and non-privileged delay memoranda shall be posted publicly on the same day they are finalized to ensure transparency and preempt "document unavailable" delays in potential litigation or FOIA requests. **All postings shall respect deliberative-process privilege and attorney work-product protections to avoid inadvertent waiver of legal privileges.**

(e) CONGRESSIONAL COORDINATION

Within **60 days** of the date of this order, the Secretary shall prepare for Presidential consideration a legislative proposal for:

(i) Permanent mutual recognition authority for insulin and other biologics;

(ii) PBM transparency and pharmacy benefit reform;

(iii) International reference pricing frameworks;

(iv) Supply chain resilience and domestic manufacturing incentives.

The proposal shall be developed in consultation with relevant Congressional committees and stakeholders to maximize bipartisan support.

The Secretary shall consult with the Department of State and the United States Trade Representative to ensure that the initial rollout of this Order does not create supply instability in allied nations, recommending a phased approach or product-specific sequencing if necessary.

(f) INTERNATIONAL COORDINATION

To prevent market destabilization in allied nations, the Secretary shall:

(i) Consult with EMA, MHRA, PMDA, and Health Canada regarding anticipated market impacts;

(ii) Prioritize products manufactured with excess global production capacity;

(iii) Consider phased rollout beginning with pilot states or specific product categories if supply concerns arise;

(iv) Monitor international pricing and availability, adjusting implementation pace if adverse impacts are detected.

(g) PRESIDENTIAL MONITORING

The President shall receive implementation summaries every **14 days** until first approvals are confirmed and quarterly thereafter. These summaries shall include:

(i) Progress against each deadline, with explanations for delays;

(ii) Obstacles encountered and resolution strategies employed;

(iii) Market indicators (applications received, products approved, prices observed);

(iv) Real-world impact data (patient access, adverse events, cost savings);

(v) Legal challenges filed and litigation status.

SECTION 6: LEGAL PROVISIONS

(a) STATUTORY AUTHORITY

This Order is issued pursuant to Article II of the Constitution and statutory authority including:

- **42 U.S.C. § 262(k)** (biosimilar and interchangeable biological products);
- **21 U.S.C. § 393** (FDA organization and general authority);
- **21 U.S.C. § 374** (FDA inspections and cooperation with foreign governments);
- **21 U.S.C. § 356c** (discontinuance or interruption in drug production; shortage response);
- Other applicable provisions of the Federal Food, Drug, and Cosmetic Act and Public Health Service Act.

This Order does not rely on 21 U.S.C. § 384 or § 804 (which govern importation of prescription drugs and explicitly exclude biological products). This Order directs FDA to exercise its existing authority over biosimilar review, regulatory reliance, and shortage response—**not importation authority.**

All actions taken under this Order are implemented as interpretations of existing statutory authority and shall not be construed as the promulgation of new rules or standards requiring formal notice-and-comment rulemaking, pursuant to the "good cause" exemption of the Administrative Procedure Act (5 U.S.C. § 553(b)(B)), given the public health crisis of insulin rationing and preventable deaths. Subsequent notice-and-comment procedures will be initiated within 90 days to ensure full public participation while addressing immediate public health needs.

(b) IMPLEMENTATION STANDARDS

All actions shall be taken:

(i) To the maximum extent permitted by law;

(ii) **As budget-neutral reallocation of existing resources, including user fees collected under the Biosimilar User Fee Act (BsUFA) and existing FDA appropriations, without requiring or authorizing new taxpayer funding.** This structure ensures implementation can proceed regardless of appropriations riders;

(iii) Consistent with the Anti-Deficiency Act and without violation thereof;

(iv) In compliance with the Administrative Procedure Act, including use of interim final guidance with subsequent notice-and-comment where appropriate;

(v) In a manner that maintains competitive neutrality and does not discriminate based on country of origin—all manufacturers must meet equivalent safety and quality standards.

(c) PRESERVATION OF FDA AUTHORITY

Nothing in this Order:

(i) Limits FDA's enforcement, inspection, or safety authority;

(ii) Creates new approval standards or diminishes existing statutory requirements;

(iii) Compels agency heads to act contrary to their independent scientific judgment;

(iv) Limits OMB's budgetary functions or existing statutory obligations.

FDA retains full discretion to apply traditional review processes where scientific or legal considerations warrant.

(d) NO PRIVATE RIGHTS CREATED

This Order is issued for internal management of the Executive Branch and creates no right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(e) SEVERABILITY

If any provision of this Order, or the application thereof to any person or circumstance, is held invalid, the remainder of this Order and the application of such provision to other persons or circumstances shall not be affected thereby.

SECTION 7: DEFINITIONS

For purposes of this Order:

(a) "Recognized foreign agency" means the European Medicines Agency (EMA), United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), or Japan's

Pharmaceuticals and Medical Devices Agency (PMDA)—agencies that apply ICH-harmonized standards equivalent to FDA's review framework.

(b) "To the maximum extent permitted by law" means subject to constitutional and statutory limits on agency authority, including the Administrative Procedure Act, Anti-Deficiency Act, and relevant provisions of the Federal Food, Drug, and Cosmetic Act and Public Health Service Act.

(c) "Priority insulin products" means the insulin products identified by the Commissioner under Section 2(a), selected based on medical need, manufacturer readiness, and supply adequacy.

(d) "Streamlined reliance pathway" means the regulatory review process established under Section 2(b) that accepts foreign agency assessments conducted under ICH-harmonized standards to minimize duplicative review while maintaining full FDA safety authority. **This is not importation—it is accelerated review based on trusted foreign assessments.**

(e) "Shortage-sensitive context" means situations determined by FDA based on documented supply constraints, public health risk assessments, or supply chain vulnerability—as identified through FDA shortage databases, ASHP reports, manufacturer notifications, or clinician surveys. International price disparities may inform but shall not solely determine shortage-sensitive designations.

(f) "FDA-verified insulin" means insulin products approved by FDA through any lawful pathway, including the streamlined reliance pathway, and subject to full FDA post-market oversight. This terminology shall be used in all public communications to emphasize continued FDA authority and safety oversight.

(g) "Regulatory reliance" means FDA's acceptance of foreign agency assessments conducted under equivalent standards, consistent with international best practices and FDA's existing legal authority—not a waiver of FDA review or safety standards.

SECTION 8: IMPLEMENTATION TIMELINE

This Order is effective immediately upon signature. Agencies shall execute the following actions with the goal of achieving market availability for lower-cost, **FDA-verified** insulin products within 60 to 120 days, consistent with law.

Deadline	Action	Responsible Agency
Day 10	Priority insulin list published with manufacturer communications	FDA

Day 15	OMB Regulatory Reform Dashboard launched with insulin initiative tracking	OMB
Day 15	Substitution guidance issued	FDA
Day 30	Streamlined reliance pathway guidance issued (interim final)	FDA
Day 30	Rapid intake process established	FDA
Day 30	Price transparency dashboard launched	CMS
Day 30	Public milestone tracker launched at HHS.gov	HHS
Day 45	Patient tools published	HHS
Day 45	Federal facility guidance published	HHS
Day 45	Payer guidance issued with voluntary registry	CMS
Day 45	Legal & Competitive Neutrality Memorandum published	HHS/DOJ
Day 60	Enforcement discretion framework announced	FDA
Day 60	Legislative proposal prepared	HHS
Day 60	Pilot pharmacy locations identified	HHS
Day 120	Notice-and-comment period initiated for final guidance	FDA

Agencies shall report delays exceeding 5 business days immediately to the President through the Implementation Coordinator, with proposed solutions. The Implementation Coordinator shall actively track progress and resolve obstacles to maintain this schedule.

COMMUNICATIONS GUIDANCE

All public communications regarding this Order shall emphasize:

"This is not importation—this is acceleration."

"We're cutting redundant reviews, not cutting corners."

"FDA-verified insulin approved by trusted regulators."

Avoid terminology such as "foreign insulin," "imported drugs," or "parallel trade." Instead use: "insulin approved through FDA's streamlined reliance pathway," "FDA-verified insulin products," or "insulin approved by multiple trusted regulators."

This framing protects the policy's legal foundation and preempts standard industry counterarguments.

IN WITNESS WHEREOF, I have hereunto set my hand this _____ day of _____, in the year of our Lord two thousand twenty-_____, and of the Independence of the United States of America the two hundred and _____.

[SIGNATURE]
PRESIDENT OF THE UNITED STATES