Docket No. BIS-2025-0022
XRIN 0694-XC120
Request for Public Comments on the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

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Comment from Ocyonbio Puerto Rico, LLC

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1. Executive summary

1. **Redundant U.S. clinical-trial requirements for biosimilars are delaying time-to-market by 24-36 months.** Europe is actively moving to curtail or eliminate confirmatory efficacy studies for well-characterized This is a simpler version of the text.biosimilars (European Medicines Agency (EMA), European Medicines Agency (EMA)), yet U.S. sponsors must still repeat these trials, diverting capital overseas and prolonging patient dependence on foreign supply chains.
2. **Regulatory review and inspection backlogs magnify the problem.** Median FDA biosimilar review time now exceeds 14 months, while pre-approval inspections can add another 6–9 months when travel or site-access issues arise.
3. **Artificial-intelligence (AI) tools can cut those timelines dramatically.** Automated dossier parsing, model-based comparability analytics, and virtual reality (VR) plant "walk-throughs" are technically mature and already piloted in other ICH jurisdictions.
4. **Delays directly undermine national security.** Every month a biosimilar or critical medicine remains offshore, the United States forfeits domestic control of quality, pricing leverage, and surge capacity.

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2. Background: Section 232 and pharmaceutical resilience

The Department of Commerce seeks input on "the feasibility of increasing domestic capacity" and "the impact of current trade policies on domestic production."
Discretionary tariffs or quotas alone will not solve the dependency problem if U.S. regulatory processes lengthen the path to market. Policy must tackle *both* manufacturing capacity *and* the regulatory friction that keeps that capacity idle.

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3. Specific issues and evidence

Issue	Current U.S. situation	International benchmark	National-security impact
Biosimilar clinical trials	Mandatory multi-arm efficacy trials even when analytical/PK similarity is proven.	EMA "Reflection Paper on a Tailored Clinical Approach" proposes default waivers for efficacy trials (European Medicines Agency (EMA)).	2-3 year launch lag; $50–$90 million extra cost per product; disincentive to build U.S. fill-finish lines.
Regulatory review	Manual, document-centric BLA review; limited use of structured data.	MHRA's "Innovation Passport" and EMA's upcoming DARWIN EU data network employ AI to triage dossiers in weeks, not months.	Slower domestic approvals exacerbate import reliance in shortages.
Pre-approval inspections	On-site, travel-dependent; COVID-19 worsened backlog.	EU/UK remote-inspection pilots use continuous video feeds, digital twins, and IIoT data.	Inspection delays leave U.S. capacity idle; imports fill the gap.

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4. Recommendations

1. **Harmonize biosimilar evidence standards with the EU by 2026.**
    - • Adopt a *default "no clinical efficacy study"* position when predictive analytics, in-vitro functional assays, and PK equivalence satisfy residual uncertainty—a stance already endorsed by EMA
    - • Issue FDA guidance enabling sponsors to replace confirmatory trials with structured AI-driven similarity assessments.
    - Make sure the product works as intended. If a developer shows that the new product is similar in function to the original, it should work the same way.
2. **Deploy AI for rolling, data-tiered review.**
    - • Create a cloud-native submission portal that ingests structured datasets (S-BOMs, eCTD 4.0 plus JSON metadata) and uses large language models to flag gaps automatically.
    - • Target a *90-day* review clock for dossiers that meet predefined similarity scores.
3. **Modernize inspectional oversight.**
    - • Authorize "digital twin" inspections where real-time sensor data, continuous video, and historical batch records are streamed to FDA auditors.
    - • Reserve physical inspections for high-risk or non-conforming sites, freeing resources for faster domestic capacity onboarding.
4. **Tie Section 232 remedies to regulatory acceleration.**
    - • Condition any tariff relief, tax credit, or loan support on a *reciprocal commitment* from FDA to complete review/inspection within a guaranteed timeframe when sponsors submit AI-readable dossiers.
    - • Expand BARDA/DOD "warm-base" contracts to include domestic biosimilar fill-finish (vials, syringes, cartridges) with real-time release via process analytical technology (PAT).

5. Conclusion

Tariffs can nudge supply chains, but **regulatory latency is the hidden choke point on U.S. pharmaceutical security.** Aligning evidentiary standards with international best practice and embracing AI-enabled review and inspection will:

- • Cut biosimilar launch timelines by up to 24 months.
- Unlock billions in private investment for U.S. fill-finish capacity; Ocyonbio is set to contribute over 60 million units per year in Puerto Rico.
- • Reduce dependence on geopolitical competitors for critical therapies.

We urge the Department of Commerce to incorporate this regulatory modernization. This is a simpler version of the text. It is easier to read and understand. The main ideas are clear and straightforward. Steps into its final Section 232 report and to coordinate closely with FDA, HHS, and Congress to implement them.

Respectfully submitted,

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