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Testimony at the FDA's public meeting on Generic Drug User Fee Amendments (GDUFA) Reauthorization

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I'm Dr. Michael Abrams, Senior Health Researcher with Public Citizen. We are a nonprofit consumer research and advocacy organization with over 1 million supporters. We have no financial conflicts of interest related to generic drug regulation.

Having reviewed the latest draft generic drug user fee amendments (GDUFA) commitments,[1] and having participated on the non-industry stakeholder side of these generic and other user fee negotiations (biosimilars, prescription drugs, and medical devices) over the last many months, I have two concrete suggestions.

First, the generics commitments should promise to create an FDA-based reporting structure that informs the public when manufacturers fail facility inspections. This system must be timely and must name the specific drugs implicated so that prescribers and consumers stay current on manufacturing problems related to their medications.

In 2025, the independent news service *ProPublica* created its own manufacturing database to fill this gap.[2] That dataset allows users to look up medications by generic name, manufacturer name, and National Drug Code numbers (on the container) to determine where a drug was manufactured and whether there were any inspection concerns associated with that facility. *ProPublica* created this resource because their reporting in 2025 specifically observed that the FDA:

a. sometimes "quietly allows" substandard factories to continue shipping drugs, even if they were banned from importation;

[1] Food and Drug Administration. GDUFA reauthorization performance goals and procedures fiscal years 2028 through 2032. https://www.fda.gov/media/194166/download?attachment. Accessed September 14, 2026.
[2] ProPublica. Look up where your generic prescription drugs were made. https://projects.propublica.org/rx-inspector/. Accessed September 14, 2026.

b. does not regularly test the quality of those imported generics, even when they are sourced from concerning facilities; and
c. routinely redacts drug names from its inspection reports.

The FDA should fix these problems with great haste. Prescribers and patients depend upon the agency for such critical information about the specific drugs they use. I and others made this inspection-database suggestion during the non-industry stakeholder meetings, apparently to no avail. We thus encourage this apparent error of omission to be corrected before any commitments are transmitted to Congress.

And second, the FDA should make specific, regulatory commitments promising to optimize the disclosure of Drug Master File[3] information so that generic makers can release "pharmaceutically equivalent" drugs soon after the last patent on a drug expires.[4] Presently, the FDA's inactive ingredient database lists the presumably inert chemical components of a drug.[5] However, this inactive-ingredient resource is not connected to *active* ingredients, and it only gives maximum, rather than more precise, concentration recommendations.[6] Separately, the Orange Book lists patents connected to a given branded drug,[7] but formal evaluations by the Federal Trade Commission suggest that those entries are often incomplete or inaccurate.[8]

Because patent thickets — sometimes even including Risk Evaluation and Mitigation Strategies (REMS) protocols[9] — are a key barrier to efficient generic drug creation, mediating reasonable information flow from brand to generic makers should be developed as an essential aspect of the FDA's drug regulatory effort and, thus, added explicitly to all written commitments.[10]

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[3] Food and Drug Administration. Drug Master File. December 12, 2025. https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs. Accessed September 14, 2026.
[4] Food and Drug Administration. FDA fact sheet: What's involved in reviewing and approving generic drug applications? https://www.fda.gov/media/99163/download. Accessed September 14, 2026.
[5] Food and Drug Administration. Inactive lingredient search for approved drug products. https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm. Accessed September 14, 2026.
[6] Malkin B. Deedar S. Spencer Fane. Q1/Q2 sameness transparency provision expected to save $800 over 10 years. February 11, 2026. https://www.spencerfane.com/insight/q1-q2-sameness-transparency-provision-expected-to-save-800-million-over-10-years/. Accessed September 14, 2026.
[7] Food and Drug Administration. Orange Book preface. January 15, 2026. https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface. Accessed September 14, 2026.
[8] Federal Trade Commission. FTC renews challenge of more than 200 improper patent listings. May 21, 2025. https://www.ftc.gov/news-events/news/press-releases/2025/05/ftc-renews-challenge-more-200-improper-patent-listings?utm_source=govdelivery. Accessed September 14, 2026.
[9] Sarpatwari A, Kohli S, Tu SS, Kesselheim AS. Patents on Risk Evaluation and Mitigation Strategies for prescription drugs and generic competition. *JAMA*. 2024;331(11):976-978.
[10] Love, J. Proposals for reform: pricing, innovation & access to biomedical products. Knowledge Ecology International. August 27, 2026. https://www.keionline.org/kei-bn-2026-5. Accessed September 14, 2026.

In summary, this comment suggests two straightforward additions to the generic drugs commitments draft, both proposing information resources: one for patients and prescribers (i.e., timely warnings about failed factory inspections), the other for manufacturers (i.e., reasonable disclosure of patent and chemical guidance regarding drugs soon to be entering the public domain). The former advances generic drug safety; the latter advances the availability of substitutes for typically high-priced brand-name drugs.

Finally, I would like to note that the two suggestions proposed here for generics are also relevant to commitments related to biosimilars. I hope the FDA is harmonizing these efforts.

Thank you.