

FDA's Transparency Roadmap

 [FDA Voices Post](#)

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In early October, the Food and Drug Administration (FDA) published a new **Transparency Roadmap** in an FDA Voices post authored by Lowell M. Zeta, Acting Chief of Staff, that lays out **five transparency-related priorities** for the agency in fiscal year 2027. The Roadmap not only shares what actions FDA has taken, but some of **what is still on the docket for the coming year**.

1

Complete Response Letters (CRLs): FDA will continue disclosing CRLs, and will pursue **rulemaking to increase transparency around applications** (like New Drug Applications, Biologics License Applications, and Abbreviated New Drug Applications) by disclosing the fact of submission of all major applications.

2

Investigational Stage and Marketing Application Lifecycle

Disclosures: FDA will encourage sponsors to make public when they file Investigational New Drug (IND) applications, work to increase company and researcher compliance with clinical trial reporting requirements, and increase post-approval scientific data disclosures, such as by publishing Clinical Study Reports. **FDA also noted its new information sharing agreement** with the U.S. Securities and Exchange Commission, stating “companies should understand that the FDA’s regulatory record is a relevant input to capital market oversight.”

3

New-Approach Methodologies (NAMs) and Novel Biomarkers: FDA noted its goal of **expanding visibility into the use of NAMs, real-world evidence, and decentralized trials** for evidence generation. The agency highlighted its recent launch of the NAM Database of Use Case Examples. FDA will also encourage increased use of the Biomarker Qualification Program and the Medical Device Development Tools Program.

4

Patient- and Consumer-Centered Product Labeling: FDA intends to issue a **final rule to require a new Patient Medication Instructions (PMI) Medication Guide** for outpatient drugs, requiring manufacturers include an FDA-approved, plain-language, one-page document with drug information in product labeling. FDA’s Human Foods Program will also maintain focus on consumer-centered approaches to regulation.

5

Compliance and Inspectional Records: FDA views direct-to-consumer (DTC) advertising regulation at the “intersection between transparency and public health protection.” In addition to enhanced enforcement under existing authorities, FDA is exploring **new rules or guidance on how DTC advertisements will be evaluated across new forms of media**. FDA also plans to publish inspection violation forms and other reports as appropriate.