Table 1. Status of 2010 Transparency Task Force Recommendations

Transparency Task Force Recommendation	Implemented?
1. FDA should expand the areas in which it provides the public with online access to public information from adverse event reports about FDA-regulated products submitted to FDA, in a format that is searchable and allows users to generate summary reports of this information, including, if known and as applicable, the trade name and/or established name of the product, dosage, route of administration, description of the adverse event, and the health outcome. Adverse event report information should continue to be disclosed with a clear disclaimer about the limits of the information.	**Mostly yes** All recommended parameters are reported in the FAERS Public Dashboard, except dose and route of administration.[1]
2. FDA should change its current practice so that comments submitted at www.regulations.gov from people self-identified as individual consumers are posted on that website in the same manner as other comments. In the Federal Register notice soliciting public comment, FDA should adequately inform commenters about the public disclosure of their comments on www.regulations.gov	**Yes** In the Frequently Asked Questions page of www.regulations.gov, it is clear that "most participating agencies" post public comments.[2] Recent Federal Register notices from FDA clearly state that comments will be publicly viewable at www.regulations.gov.[3]
3. In the weekly FDA publication, FDA Enforcement Report, FDA should disclose when the U.S. Department of Justice files a case seeking enforcement action on FDA's behalf in a court of law and the final determination of that case, if known.	**No**
4. FDA should post on its website all Agency Workplans (i.e., the annual Office of Regulatory Affairs Annual Field Workplan) that are older than five years, starting with the FY 2001 Workplan.	**Yes** Past Office of Regulatory Affairs/Office of Inspections and Investigations work plans are posted on FDA's website.[4]
5. FDA should disclose the outcome of the filer evaluation for importers or third parties working on behalf of importers.	**Yes** FDA Filer Evaluation Outcomes can be downloaded on FDA's website.[5]
6. FDA should disclose the name and address of the entity inspected, the date(s) of inspection, type(s) of FDA-regulated product involved, and the final inspectional classification—Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI)—for inspections conducted of clinical trial investigators, Institutional Review Boards (IRB), and facilities that manufacture, process, pack, or hold an FDA-regulated product that is currently marketed. The disclosure of this information should be timed so as not to interfere with planned enforcement actions.	**Yes** Inspection information is available on FDA's Inspections Data Dashboard.[6]
7. FDA should generate, and share with the public, information about the most common inspectional observations of objectionable conditions or practices that are made during inspections of FDA-regulated establishments and post that information online on a regular basis.	**Yes** Most common citations are summarized on FDA's Inspections Data Dashboard.[6]

8. FDA should disclose the existence and, when asked, confirm the existence or non-existence of investigational applications. For investigational applications, the disclosure should include the name of the application sponsor, the date the application was received, the proposed indication(s) or intended use(s) of the product, and the proposed proper and/or trade name of the product, if available.	**No**
9. FDA should disclose: (1) whether an investigational new drug application (IND) has been placed on hold, terminated, or withdrawn, whether an investigational device exemption (IDE) has been terminated or withdrawn, or whether an investigational exemption for a new animal drug has been terminated and (2) if an IND has previously been placed on hold, whether and when the hold is lifted. A statement should be included that such actions may be taken for various reasons, only some of which relate to safety or effectiveness.	**No**
10. FDA should disclose the fact that an NDA, NADA, ANDA, ANADA, BLA, PMA, or 510(k) application or supplement was submitted (or resubmitted) to the Agency at the time the application is received by FDA. The disclosure should include the name of the application sponsor, the date the application was received, the proposed indications or intended use of the product, and the proposed proper and/or trade name of the product, if available.	**No**
11. FDA should disclose that an unapproved NDA, ANDA, NADA, ANADA, BLA, or PMA, or uncleared 510(k) has been withdrawn or, if FDA determines that the application was abandoned, abandoned by the sponsor. If the drug, biological product, or device is associated with a significant safety concern, FDA should provide a brief description of the product, the use for which approval was sought or obtained, and the identified safety concern.	**No**
12. When an application for a designated orphan drug or a designated minor use/minor species animal drug has been withdrawn, terminated, or abandoned, FDA should disclose, if it determines, based on its review, that the application was not withdrawn, terminated, or abandoned for safety reasons and the product, if approved, could represent a significant therapeutic advance for a rare disease or for a minor animal species. A disclaimer that provides that FDA's expressed views about the product do not reflect whether a subsequent application involving the product will be accepted for filing or will be approved by FDA should accompany the disclosure of this information.	**No**

13. FDA should disclose the fact that the Agency has issued a refuse-to-file or complete response letter in response to an original NDA, BLA, or an efficacy supplement for an NDA or BLA at the time the refuse-to-file or complete response letter is issued, and should, at the same time, disclose the refuse-to-file or complete response letter, which contains the reasons for issuing the letter.	**Yes, partially** In July of 2025, FDA published over 200 Complete Response Letters (CRLs),[7] most of which were already publicly available. In September 2025, FDA released 89 more CRLs for unapproved products that had not previously been disclosed.[8] FDA officials have stated a desire to release CRLs in real-time.[8] The legality of this practice, without first changing regulations, has been questioned.[9] Analogous documents related to devices, foods, veterinary medicines, and tobacco products have not been released. Refuse-to-file letters are not disclosed.
14. FDA should disclose the fact that the Agency has issued a refuse to approve letter in response to a NADA, or a supplemental NADA to add a new species or indication, at the time the refuse to approve letter is issued, and should, at the same time, disclose the refuse to approve letter, which contains the reasons for issuing the letter.	**No**
15. FDA should disclose the fact that the Agency has issued a "not approvable" letter in response to a PMA for a medical device and the fact that FDA has issued an "additional information (AI)" letter in response to a 510(k) submission, and should, at the same time, disclose the "not approvable" letter or "additional information (AI)" letter, which contains the reasons for issuing the letter.	**No**
16. FDA should disclose relevant summary safety and effectiveness information from an investigational application, or from a pending marketing application, if the Agency concludes that disclosure is in the interest of the public health, which includes when FDA believes it is necessary to correct misleading information about the product that is the subject of the application.	**No** FDA has the authority to disclose this information, but we are not aware of any circumstances in which it has used that authority outside of sharing information for advisory committees. For device PMAs, 21 CFR 814.9(d)(1) stipulates that FDA may "disclose a summary of portions of the safety and effectiveness data before an approval order or an order denying approval of the PMA issues if disclosure is relevant to public consideration of a specific pending issue."[10] For drug product applications, 21 CFR 314.430(d)(1) stipulates "the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue; for example, for consideration of an open session of an FDA advisory committee."[11]

17. FDA should convene a group of internal and external stakeholders to discuss the possible uses of non-summary safety and effectiveness data from product applications, the circumstances under which it would be appropriate for sponsors to disclose non-summary safety and effectiveness data from applications submitted to FDA, and if appropriate, the format and the method by which disclosure should occur.	**No**
18. When a system is set up that provides FDA with authority to require companies to submit certain information to the Agency when they initiate an action to recover or correct a product that is in the chain of distribution, FDA should disclose this information as soon as practicable after receiving this information from the firm.	**No** When a recall is initiated, FDA may request information from the recalling firm.[12] FDA does not routinely disclose information it receives.
19. FDA is aware of confusion in the marketplace about products that may be implicated in a food outbreak, and information gathered by industry or other sources may serve to alleviate that confusion, FDA should support efforts by industry and others to communicate information to the public about products that are not subject to the recall when sufficiently reliable information about products not connected with the recall exist, if FDA concludes that disclosure of this information is in the interest of public health.	**No** An FDA webpage posted in 2014 references its role in communicating to the public about products not subject to a 2009 pistachio recall (before this recommendation was made).[13] We are not aware of any other instances in which FDA communicated about products not subject to an ongoing recall.
20. If FDA determines that a recall is terminated, that information should be disclosed to the public. A recall is considered terminated when FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy and when it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed.	**Yes** The recall list, available on FDA's website, specifically identifies recalls that have been terminated.[14]
21. FDA should post untitled letters on the FDA website, and, if requested by the recipient of the letter, the response to the untitled letter, as proper.	**Yes, partially** FDA's website now states that, in some instances, Untitled Letters are proactively posted to its website.[15]

References

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[2] General FAQs. Accessed August 28, 2025. https://www.regulations.gov/faq

[3] *88 FR 68006. Medical Devices; Laboratory Developed Tests*. Accessed August 28, 2025. https://www.federalregister.gov/documents/2023/10/03/2023-21662/medical-devices-laboratory-developed-tests

[4] U.S. Food and Drug Administration. OII Workplans. FDA. May 7, 2025. Accessed August 28, 2025. https://www.fda.gov/about-fda/oii-foia-electronic-reading-room/oii-workplans

[5] U.S. Food and Drug Administration. Filer Evaluations. FDA. August 5, 2025. Accessed August 28, 2025. https://www.fda.gov/industry/actions-enforcement/filer-evaluations

[6] U.S. Food and Drug Administration. FDA Dashboards - Inspections. Accessed April 2, 2025. https://datadashboard.fda.gov/ora/cd/inspections.htm

[7] U.S. Food and Drug Administration. FDA Embraces Radical Transparency by Publishing Complete Response Letters. FDA. July 10, 2025. Accessed August 28, 2025. https://www.fda.gov/news-events/press-announcements/fda-embraces-radical-transparency-publishing-complete-response-letters

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[9] Dickos PG, Butler ML, Wicks S. CRLs Today, (Potential) Lawsuits Tomorrow. FDA Law Blog. September 16, 2025. Accessed October 21, 2025. https://www.thefdalawblog.com/2025/09/crls-today-potential-lawsuits-tomorrow/
[10] *21 CFR §814.9. Confidentiality of Data and Information in a Premarket Approval Application (PMA) File*. Accessed May 2, 2025. https://www.ecfr.gov/current/title-21/section-814.9
[11] *21 CFR §314.430. Availability for Public Disclosure of Data and Information in an Application or Abbreviated Application*. Accessed May 6, 2025. https://www.ecfr.gov/current/title-21/section-314.430
[12] *21 CFR §7.40. Recall Policy*. Accessed August 28, 2025. https://www.ecfr.gov/current/title-21/section-7.40
[13] U.S. Food and Drug Administration. Assisting Interested Parties in Addressing Marketplace Confusion Over the Identity of Products Subject to Recall. FDA. December 26, 2019. Accessed August 28, 2025. https://www.fda.gov/safety/industry-guidance-recalls/assisting-interested-parties-addressing-marketplace-confusion-over-identity-products-subject-recall
[14] U.S. Food and Drug Administration. Recalls, Market Withdrawals, & Safety Alerts. FDA. October 1, 2024. Accessed August 28, 2025. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
[15] U.S. Food and Drug Administration. Issuance of Untitled Letters. *FDA*. Published online August 9, 2024. Accessed August 28, 2025. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/issuance-untitled-letters