Table 2. Changes necessary to implement report recommendations

Recommendation	Required Change	Comments
Unimplemented Recommendations from the *Blueprint for Transparency at the U.S. Food and Drug Administration*		
1. FDA should disclose basic information (including name of sponsor and product) about investigational notices, the filing of marketing applications, and the existence of clinical holds.	Statutory change may be required.[a] Regulatory change required.	See note on exemption 4, below. If FDA makes clear at the time of submission that it will not treat the submission as confidential, FOIA should not be a barrier to disclosure. Revision to either the FDCA or to FOIA exemption 4, however, could facilitate routine disclosure. Regulatory change required because 21 CFR § 312.130 provides that FDA will not release information about an IND if the sponsor has not done so and 21 C.F.R. § 314.430(b) provides the same for NDAs.[b,c] Previously confidential information is no longer confidential once the sponsor discloses it. Therefore, when a sponsor has disclosed basic information about pending INDs or marketing application, the FDA can and should disclose the information addressed in this recommendation as well.
2. FDA should include in disclosures of investigational notices and marketing applications the class of medication and mechanism of action if known.	Statutory change may be required. Regulatory change required.	See #1, above.
3. Where FDA enters into a Special Protocol Assessment, FDA should release the text relevant to safety and efficacy after the study is completed.	Statutory change may be required. Regulatory change required.	See #1, above.

[a] Throughout, the contemplated statutory change includes either the FDCA or FOIA, unless otherwise noted. The recommended action could be protected from adverse court action by statutory change.

[b] Section 340(b) states; "FDA will not publicly disclose the existence of an application or abbreviated application before an approval letter is sent to the applicant under § 314.105 or tentative approval letter is sent to the applicant under § 314.107, unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged." Accordingly, FDA may release summaries of selected portions of safety and effectiveness information in a pending application if the existence of the application has been publicly disclosed or acknowledged by the sponsor, if relevant for public consideration of a specific pending issue. This exception is most commonly invoked when an advisory committee meeting is held to consider an application prior to its approval or clearance. Also, under the Best Pharmaceuticals for Children Act (BPCA) (which applies to human drug applications) and the Pediatric Research Equity Act (PREA) (which applies to both human drugs and biological products), FDA must release clinical, clinical pharmacology, and statistical reviews of pediatric studies within a statutorily defined time frame regardless of whether the application has been approved. See https://www.ipqpubs.com/wp-content/uploads/2010/06/FDA_Transparency_Task_Force.pdf, at pages 36–37.

[c] Of potential use in arguing for more transparency, one study found that information that the FDA treats as confidential with regard to applications for NDAs was in most cases already available to the public. The disclosure rate in 2016 was 97.6%. Most disclosures took place in press releases, SEC filings, or both and occurred within 1 week of application submission. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6547098/.

4. When FDA has issued or released a clinical hold related to safety to efficacy, the FDA should release a summary of the reasons within 10 days.	Statutory change may be required.	See #1, above.
5. FDA should disclose whether a marketing application has been designated for an expedited development or review program and, if so, provide the scientific basis for that designation.	Statutory change may be required.	See #1, above.
6. FDA should disclose written requests for pediatric studies at the time such requests are made, as well as other documents indicating agreement on changes to the initial request.	a) Statutory change may be required; regulatory change required. b) Policy	a) For NDAs not yet approved, see #1, above. b) For approved NDAs, no barrier. Note that requests made at the time of initial approval are often disclosed in the NDA approval letter.
7. FDA should provide information and explanations for withdrawn applications and should disclose FDA's letter to the sponsor communicating that the product is not approved.	Statutory change may be required. Regulatory change recommended.	See #1, above. For example, 21 CFR 314.430(d) states that "If the existence of an application or abbreviated application has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application or abbreviated application is available for public disclosure before the agency sends an approval letter …" Under 21 USC 355(l), some information should be disclosed "upon request" when a product is not approved. That section doesn't require the agency proactively to disclose, however. In addition, if the sponsor says that it is still working on the application, 355(l) does not require disclosure, and FDA's policy is not to disclose.
8. FDA should make public its clinical and statistical reviews of products not approved or for which the marketing applications are abandoned or withdrawn. FDA should issue guidance on the definition of abandonment.	a) Either regulatory change or policy change required. b) Depends (see comment). c) Statutory change may be required; regulatory change required.	a) Under 21 USC 355(l), information as to applications that have been abandoned – that is, "no work is being done or will be undertaken to have the application approved" – "shall" be disclosed to the public "upon request." FDA could do so proactively, as a matter of policy or regulation. b) Under 21 USC 355(l), information as to products for which the NDA was withdrawn by the sponsor "shall" be disclosed upon request only if the FDA has determined that the product is "not approvable." c) If FDA does not approve but the sponsor says that it is not abandoning the product, 355(l) does not require disclosure. In that circumstance, disclosure would turn on application of FOIA exemption 4.

9. FDA should make its pooled data sets masked and de-identified as appropriate, and FDA should make its analyses of these data sets available to the medical and research community through clinical data repositories, such as through the National Institutes of Health Biologic Specimen and Data Repository Information Coordinating Center.	Policy change required.	
10. FDA should disclose the filing of generic drug applications, including the name of the sponsor and the name of the reference drug to be copied.	Statutory change may be required (assuming confidential). Regulatory change required.	See #1, above.
11. FDA should routinely disclose those portions of Complete Response Letters to generic drug manufacturers that relate to bioequivalence.	Statutory change may be required (assuming confidential). Regulatory change required.	See #1, above, which applies to ANDAs.
12. FDA should routinely disclose the filing of abbreviated biologics licensing applications, including the name of the sponsor, the reference biologic product, and whether the application is for "biosimilarity" or "interchangeability."	Statutory change may be required (assuming confidential). Regulatory change required.	See #1, above. Similarly, disclosure of biologics applications is barred by 21 CFR § 601.51(b), unless the sponsor has already disclosed its existence. It appears that FDA treats this regulation as applying to abbreviated biologics licensing applications.
13. FDA should routinely disclose those portions of a Complete Response Letter with respect to an abbreviated biologics licensing application that relate to the biosimilarity to or interchangeability with the reference biologic product.	Statutory change may be required (assuming confidential). Regulatory change required.	See #12, above.
14. FDA should correct misleading information where there is the potential for substantial confusion about the safety or efficacy of the medical product for both approved and unapproved uses.	Policy change required.	
15. FDA should disclose Clinical Study Reports that have been submitted to FDA in support of a marketing application. To the extent possible, FDA should harmonize standards on CSR release with the European Medicines Agency.	Pre-approval Statutory change may be required. Regulatory change required. Post-approval Statutory change may be required.	Pre-approval: See #1, above. Post-approval: See note on exemption 4.

16. FDA should release the final reports that fulfill Postmarketing Requirements and Postmarketing Commitments, including Clinical Study Reports of Phase IV Studies and other post-approval reports, at the time FDA considers the sponsor's obligation to conduct a study to be fulfilled.	Statutory change may be required. Policy change required.	See note on exemption 4. If FDA makes clear at the time of submission that it will not treat the submission as confidential, FOIA should not be a barrier to disclosure. Revision to ether the FDCA or to FOIA exemption 4, however, could facilitate routine disclosure.
17. When there are clinical trial data, including patient-level data, that are not available to independent investigators through industry-sponsored websites, then FDA should make data available through clinical data repositories, such as through the National Institutes of Health Biologic Specimen and Data Repository Information Coordinating Center, with policies on deidentification to protect patient privacy.	Policy change required.	
New Recommendations		
18. FDA should release refuse-to-file letters sent to sponsors when their applications cannot be reviewed.	Statutory change may be required. Regulatory change required.	See #1, above.
19. FDA should proactively post approval packages for supplemental indications.	Policy change required.	
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.	Policy change required.	
21. FDA should proactively disclose annual reports on Risk Evaluation and Mitigation Strategies (REMS) reports submitted by product manufacturers.	Policy change required.	
22. FDA should proactively disclose Periodic Benefit-Risk Evaluation Reports submitted by product manufacturers.	Policy change required.	

23. FDA should increase the transparency of Advisory Committee meetings by disclosing Section 502 conflicts of Advisory Committee members.	Policy change required.	
24. FDA should proactively release Establishment Inspection Reports (EIRs) and post Form 483s.	Policy change required.	
25. FDA should disclose the existence and results of safety investigations.	Policy change required.	
26. Transparency can be enhanced with methods beyond document disclosures.	Change in FDA's internal norms required.	
27. FDA should correct misleading information related to products it regulates, taking into account developments in the law and impact of social media.	Change in FDA's internal norms required.	
28. FDA should tailor its transparency efforts to consider the intended audience.	Change in FDA's internal norms required.	
29. FDA can leverage SEC disclosure requirements to increase industry transparency.	Other	
30. FDA should conduct additional research on transparency, including studies that report deidentified aggregate data summarizing documents currently not disclosed.	Other	
31. FDA should close the GRAS loophole for food chemicals.	Statutory and/or regulatory change required.	
32. FDA should prioritize implementation of transparency recommendations that fall within its existing authority, while also advocating for statutory changes necessary to implement other recommendations.	Other	

Note on FOIA exemption 4:

Under exemption 4 as currently interpreted, information is exempt from disclosure under FOIA if (1) the sponsor keeps the information confidential, and (2) the agency provides assurance that it will keep the information confidential. However, the Department of Justice has advised agencies that the assurance may be express pr implied, and that implied assurance exists if the agency does not indicate at the time of submission of the information that the agency will disclose it. Thus, although the FDA could decide to release information (other than trade secrets) that is subject to exemption 4 by indicating that it will do so, FDA in practice does not do so. Therefore, for many of the items above, a change to agency practice, and possibly to FOIA exemption 4, would be required.