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Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Comments on the Food and Drug Administration's June 27, 2019, *Federal Register* Notice Requesting Comments on the Agency's New Drugs Regulatory Program Modernization: Improving Approval Package Documentation and Communication
Docket No. FDA-2019-N-2012

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, submits these comments in response to the Food and Drug Administration's (FDA's) June 27, 2019, request for comments referenced above.[1]

Public Citizen strongly objects to the FDA's proposal to use and publicly post, upon approval of a new drug applications or biologics license application, an abbreviated integrated review document *in place of* the more detailed individual medical, chemistry, pharmacology, statistical, clinical pharmacology biopharmaceutics, and risk assessment and risk mitigation reviews, among others, that have been prepared and regularly posted on the FDA website for many years. According to the Federal Register Notice, the integrated review document not only "would replace the current documentation where each discipline provides a separate application review document" but "would be a collaborative document with input from clinical, clinical pharmacology, biostatistics, [and] toxicology reviewers, and other disciplines based upon the issues raised by the application."

This ill-conceived proposal would, at the least, be a major step backwards in agency transparency with respect to the data that the agency relies on when approving new drugs or biologics and the agency's assessment of these data. In particular, the posting of an integrated review document in lieu of posting reviews by each discipline as is currently done would conceal from the public valuable information and data, including the following:

- The rich, informative details about each FDA discipline's review and assessment of the application, including detailed animal toxicology data and clinical trial data on published and unpublished trials supporting the safety and efficacy of the product
- Concerns with the application raised by individual FDA reviewers that were excluded from the integrated review document because they were judged not to be significant enough to be included in the collaborative review

[1] 84 FR 30733.

- Key contextual information and granularity of detail that would provide a robust understanding of individual FDA reviewers' concerns, as well as the basis for the FDA's overall decision to approve the application
- Detailed documentation of the reasons some reviewers might have to recommend that an application not be approved
- Detailed documentation of any differences of opinion between FDA reviewers
- Detailed clinical trial data on often unpublished trials

But beyond the issue of transparency of reviews, all of which are disclosable under the Freedom of Information Act, it is unclear from the FDA's description of the proposal for use of the integrated review document whether individual agency reviewers in each discipline would even continue to write separate review documents, as currently occurs. Our concern in this regard is heightened by the FDA's statement about assessing the "efficiency" of these current individual review documents in the "regulatory decision-making process." Eliminating the production of such review documents by the individual disciplines could lead to dangerous groupthink and inhibit the expression of important minority views, further undermining the FDA's review and approval process for drugs and biologics and threatening public health. This groupthink concern is corroborated by the replacement of the individual disciplines' reviews with a "collaborative document."

Finally, we are troubled to learn that the FDA apparently already had begun implementing this proposal before the agency has received all public comments on it (see for example the reviews for erdafitinib [BALVERSA],[2] posted on May 9, and for ferric maltol [ACCRUFER][3], posted on August 14).

We certainly would not object to the production and posting of an integrated review document as a *supplement* to the production and posting of separate review documents by each agency discipline. But doing away with the latter would make this one of the most dangerous proposals by the FDA in years and must not be permitted.

Thank you for the opportunity to comment on this critically important public health issue.

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[2] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212018Orig1s000TOC.cfm. Accessed August 21, 2019.

[3] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212320Orig1s000TOC.cfm. Accessed August 21, 2019.