NATIONAL HEALTH COUNCIL
Celebrating 100 Years

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December 23, 2020

The Honorable Stephen Hahn
Commissioner
U.S. Food and Drug Administration
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

On behalf of the National Health Council (NHC), I am pleased to provide the following comments in response to the Integrated Assessment of Marketing Applications Virtual Workshop. These written comments will supplement my oral comments at the workshop.

Created by and for patient organizations 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 140 national health- related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The NHC supports the goals of the FDA's initiative to modernize the New Drugs Regulatory Program, using 21st Century technology to streamline the review process; bring new and better products to patients faster; and improve communication between sponsors, reviewers, patient organizations, and the general public. As such, we believe integrated assessment of marketing applications is a step forward, and we offer general support and a few recommendations to improve the process.
By using a team-based, interdisciplinary model that effectively communicates the basis for new drugs and increasingly incorporates the patient perspective, the FDA can greatly improve communication with current and future sponsors and the general public. Currently, documentation requires each discipline, such as clinical, clinical pharmacology, biostatistics, toxicology reviewers, and

others, to submit a separate review. These action packages are currently posted on the FDA website but can be cumbersome to navigate because of their length.
The new document would improve upon this by including three components:

- Executive summary (including risk/benefit analysis),
- Interdisciplinary assessment, and
- Discipline-Specific Appendices.

Moving to a coordinated review should improve communication between different review teams providing a more streamlined review of drugs and biologics. For instance, the use of an integrated review template would provide more clarity for stakeholders, including patients, who want to gain a more granular understanding of FDA decisions.
There are several clarifications that the NHC requests to make the review document more comprehensive and useful.

- First, the expected components of the review document do not specifically discuss the need for collecting patient-experience data. Making sure that patient experience data is part of the components is necessary to ensure assessments are truly addressing patient needs.
- Second, we recommend that the benefit/risk analysis include a discussion of how patient-experience data influenced the agency's decision. Again, this will help ensure that patients' experiences and needs are reflected in the assessment.
- The NHC also recommends the FDA consider incorporating a nontechnical abstract or document that describes the decision in layman's terms to ensure transparency, clarity, readability, and usability for patients and other non-technical audiences.
- Finally, we ask the FDA to assure that the new system include documentation from previous approvals. Some stakeholders have expressed concerns around a reduction in data/information that will be publicly available with the new system. Many newer drug sponsors use previous approvals to understand FDA's decision-making process for approval, and without the detailed documentation, these sponsors may have delays in applying and approval of valuable drugs for patients.

We appreciate the opportunity to provide input on this important issue. Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

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