September 11, 2018

Honorable Scott Gottlieb, MD
Commissioner, Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Patient-Focused Drug Development: Collecting Comprehensive and Representative Input; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders (Docket No. FDA-2018-D-1893)

Dear Commissioner Gottlieb:

On behalf of the more than 8 million Americans living with psoriatic disease, the National Psoriasis Foundation (NPF) appreciates the opportunity to comment on the Food and Drug Administration’s (FDA) Patient-Focused Drug Development (PFDD): Collecting Comprehensive and Representative Input; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders. As the patient advocacy organization for the psoriatic disease community for over 50 years, the NPF shares the FDA’s goal of expanding the patient role in drug development and applauds the emphasis on patients as partners.

We commend the FDA’s efforts to actively engage patients by expanding the use of patient experience data throughout the drug development process. As you know, disease-specific patient-focused drug development meetings, like the March 17, 2016, event that focused on psoriasis, highlighted that patient perspectives and experiences are often missing, or incorporated too late, in the development process. As such, we are encouraged by the FDA’s continued focus on expanding the role of patients and the Agency’s thoughtful approach to evolving this work.

Specifically, we appreciate the emphasis the draft guidance places on the role of patient experience data during the clinical trial phase but question whether the focus on clinical trials could undermine the value of patient input in other phases. To address this, we recommend the FDA outline specific ways that patient experience data and conversations with patients and other stakeholders can inform the research process from start to finish. To the same aim, we urge the FDA to provide additional details on the ways stakeholders, including patient groups, can engage with the Agency in an effort to more formally operationalize patient involvement in the development process. As members of the National Health Council, we strongly encourage you to review their submitted comments where you can find further comments in these areas and others.

The NPF is grateful for our ongoing partnership with the FDA and we look forward to engaging as the guidance process moves forward. If you or your colleagues have any questions, please contact Jessica Nagro, Federal Government Relations and Health Policy Manager (jnagro@psoriasis.org, 503-546-5559). Thank you in advance for your consideration.

Sincerely,

Patrick Stone
Vice President, Government Relations & Advocacy