February 16, 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: Guidance 1 – Collecting Comprehensive and Representative Input (Docket No. FDA-2017-N-5896)

Dear Commissioner Gottlieb:

On behalf of the more than 8 million Americans living with psoriasis and psoriatic arthritis, the National Psoriasis Foundation (NPF) appreciates the opportunity to provide comments on the Food and Drug Administration’s (FDA) Patient-Focused Drug Development: Guidance 1 – Collecting Comprehensive and Representative Input. We commend the FDA’s deep commitment to increasing patient engagement in the development process and appreciate the continued efforts to refine and enhance this work that are evident in the guidance document.

As the patient advocacy organization for the psoriatic disease community for more than 50 years, the NPF shares the FDA’s goal of improving data collection and input so clinical studies more accurately reflect patient and caregiver needs. We are encouraged to see the agency moving to build upon the recent disease-specific patient-focused drug development meetings, like the March 17, 2016, event that focused on psoriasis. As that meeting highlighted, patient perspectives and experiences are often missing, or incorporated too late, into the development process. The FDA’s ongoing commitment to improving this practice will go a long way in increasing understanding of disease burden and ensuring that treatments are not only safe and effective but also address the most pressing needs of patient communities.

For additional feedback, we encourage you to review the comments submitted by the National Health Council in response to this request for stakeholder input. The NPF is excited to engage with the FDA as the guidance process moves forward so please contact Jessica Nagro, Federal Government Relations and Health Policy Manager (jnagro@psoriasis.org, 503-546-5559), with any questions or requests. Thank you in advance for your consideration.

Sincerely,

Patrick Stone
Vice President, Government Relations and Advocacy