September 7, 2018

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lan, Rm. 1061
Rockville, MD 20852

RE: Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products-Content and Format; Draft Guidance for Industry

Dear Commissioner Gottlieb:

The American Association of Nurse Practitioners (AANP) is the largest full-service national professional membership organization for nurse practitioners (NPs), which represents the more than 248,000 nurse practitioners across the country. We thank you for the opportunity to comment on the FDA's draft guidance for the indications and usage section of labeling for human prescription drug and biological products.

NPs are advanced practice registered nurses who are prepared at the masters or doctoral level to provide primary, acute, chronic and specialty care to patients of all ages and walks of life. Daily practice includes: assessment; ordering, performing, supervising and interpreting diagnostic and laboratory tests; making diagnoses; initiating and managing treatment including prescribing medication and non-pharmacologic treatments; coordinating care; counseling; and educating patients and their families and communities. NPs practice in nearly every health care setting including clinics, hospitals, Veterans Affairs and Indian Health Care facilities, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), nursing homes, schools, colleges, retail clinics, public health departments, nurse managed clinics, homeless clinics, and home health. NPs hold prescriptive authority in all 50 states and the District of Columbia. It is important to note that 86.6% of NPs are certified in primary care, the majority of whom see Medicare and Medicaid patients. NPs complete more than one billion patient visits annually.

We look forward to working with the FDA on industry guidance and the best ways to disseminate this necessary information to health care providers and other stakeholders. We continue to encourage the FDA to include nurse practitioners in all advisory panels and activities. Nurse practitioners play a vital role in our health care system and must be included in all initiatives. As we have noted previously, this inclusion extends to all communications, regulations and guidance in order to ensure that the patients of nurse practitioners have access to medically necessary drugs and devices.

Provider Neutral Labeling

We thank the FDA for using provider neutral language throughout this draft guidance, and we continue to encourage the FDA to use this language in all communications, guidance and regulations. While the

FDA did use provider neutral language in this guidance, other FDA regulations still mandate that over-the-counter (OTC) medications and other products containing certain ingredients use warning labels instructing purchasers to consult their "doctor" or "physician."[1] Other qualified healthcare providers, including nurse practitioners, are the primary or attending providers for patients using that medication or product and are licensed and qualified to provide this information. The FDA has used the phrase "health professional" in labeling a number of products,[2] and "health care practitioner" throughout this draft guidance. This is not cumbersome and more accurately reflects the broader scope of clinicians who are licensed and qualified to treat patients.

The use of the term "physician" or "doctor" on the label confuses patients regarding which qualified clinicians are authorized to provide care and undermines the scope of practice and quality of care provided by nurse practitioners. This can lead to unfair restraints on practice, an unfair competitive advantage in the healthcare marketplace and decreased access to care for patients. The use of provider neutral labeling is also necessary to ensure that when payors are drafting prior authorization and other coverage policies, they do not unnecessarily create a physician order requirement, which can lead to delays in treatment when the patient is seeing an NP or other qualified health professional. It is important that the FDA updates outdated regulations and guidance that utilize the word "physician" when other qualified health professionals, such as NPs, are licensed and qualified to treat patients using these medications and products.

We thank the FDA for using provider neutral language throughout this draft guidance and we look forward to working with the FDA on reducing regulatory barriers for nurse practitioners and their patients. Should you have comments or questions, please direct them to MaryAnne Sapio, V.P. Federal Government Affairs, msapio@aanp.org, 703-740-2529.

Sincerely,

David Hebert
Chief Executive Officer

[1] 21 CFR § 201.66.
[2] 21 CFR § 201.63, 21 CFR § 201.320, 21 CFR § 201.325, 21 CFR § 801.63.