October 4, 2018

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

RE: Docket No. FDA-2014-N-1048 for "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Regulations."

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 comment request for medical device labeling regulations.

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 regulations and guidance and the best ways to disseminate this necessary information to health care providers and other stakeholders. We also appreciate that recent draft guidance issued by the FDA has used provider neutral language. 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.

Medical Device Labeling Regulations

The FDA requested comment on medical device labeling regulations. We continue to encourage the FDA to use provider neutral language in all communications, guidance and regulations. In that vein, we request that the warning label requirement for sunlamp products contained in 21 CFR § 1040.20(d)(1)(i) be updated to replace the term "physician" with "practitioner" to better reflect that other qualified health care providers, such as NPs, can be consulted regarding the potential side effects of using a sunlamp product. "Practitioner" is used in other regulations referenced in this comment request and using this language in 21 CFR § 1040.20(d)(1)(i) will create consistency throughout the FDA regulations. We believe that this was an oversight given the other language in the regulations and recent guidance issued by the FDA which has been consistently provider neutral.

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 appropriate care for patients. The use of provider neutral labeling is 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, such as those regarding the labeling of over-the-counter (OTC) medications, 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.

The FDA has used the phrase "health professional" in labeling a number of products,[1] and "practitioner" in other labeling regulations. This is not cumbersome and more accurately reflects the broader scope of clinicians who are licensed and qualified to treat patients. We request that the FDA continue to update outdated regulations with provider neutral language.

We thank the FDA for the opportunity to comment on these regulations 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 § 201.63, 21 CFR § 201.320, 21 CFR § 201.325, 21 CFR § 801.63.