



Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

November 6, 2025

Re: Development of Non-Opioid Analgesics for Chronic Pain (Docket No. FDA-2025-D-0610)

To Whom It May Concern:

On behalf of the more than 69,000 members of the American Association of Nurse Anesthesiology (AANA), we submit these comments in response to the draft guidance titled "Development of Non-Opioid Analgesics for Chronic Pain." AANA is the professional association representing Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs) nationwide. CRNAs are advanced practice registered nurses (APRNs) who are autonomous anesthesia providers with extensive education and clinical training. AANA welcomes the opportunity to provide feedback on this draft guidance related to chronic pain management which impacts CRNAs and the patients and facilities they serve.

We submit the following comments regarding this draft guidance:

- CRNAs, as experts in chronic pain management, are educated and trained to integrate new and emerging non-opioid techniques and medications into treatment.
- Based on the definition of chronic pain, studies should be appropriately designed to assess medication treatments for greater than 12 weeks to better reflect real-world clinical chronic pain scenarios.
- AANA would like to remain a resource to the FDA to further support the agency in any chronic pain management initiatives.

CRNAs, as experts in chronic pain management, are educated and trained to integrate new and emerging non-opioid techniques and medications into treatment.

The AANA recognizes that a significant percentage of patients suffer from chronic pain, underscoring the importance of precise and effective treatment options. The opioid crisis remains a significant public health challenge, particularly in light of chronic pain management. Despite recent declines in opioid prescribing¹, opioids are still commonly used by healthcare providers for patients with chronic pain, underscoring the need for effective non-opioid analgesics to reduce opioid reliance and improve patient outcomes.

¹ Centers for Disease Control and Prevention. Opioid Dispensing Rate Maps. <https://www.cdc.gov/overdose-prevention/data-research/facts-stats/opioid-dispensing-rate-maps.html>. Accessed Oct 21, 2025.

CRNAs are helping to reduce the opioid crisis by utilizing a multimodal approach to the management of chronic pain, which includes non-opioid therapies.^{2,3} The multimodal approach that CRNA pain management practitioners employ when treating their patients may reduce the reliance on opioids as a primary pain management modality, thus aiding in the reduction of potential adverse drug events related to opioids. By leveraging a combination of pharmacologic and non-pharmacologic treatments, this approach mitigates patient risk of substance use disorder by minimizing opioid exposure. Additionally, CRNAs are poised to integrate new and emerging technologies and medications, including non-opioid therapies, into their clinical practice to further enhance patient safety and outcomes.

Based on the definition of chronic pain, studies should be appropriately designed to assess medication treatments for greater than 12 weeks to better reflect real-world clinical chronic pain scenarios.

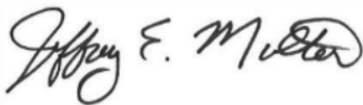
According to the International Association for the Study of Pain, chronic pain is defined as “pain that persists or recurs for longer than 3 months.”⁴ Given this duration to assess for chronic pain, the AANA recommends that the FDA incorporate a duration of greater than 12 weeks for non-opioid analgesic treatment targeting chronic pain to verify proper differentiation from acute pain and to better reflect real-world clinical chronic pain scenarios. We acknowledge FDA’s concern that a longer study duration may cause patients to discontinue from the trial, particularly in the placebo study arm, which can impact data completeness and generalizability. The FDA may also consider pragmatic trial designs or longitudinal data collection methodologies to capture treatment adherence, discontinuation patterns, and long-term outcomes reflective of typical chronic pain patient populations.

AANA would like to remain a resource to the FDA to further support the agency in any chronic pain management initiatives.

The AANA is available and willing to continue our engagement with the FDA regarding chronic pain and non-opioid therapy research and integration into clinical practice. The CRNA community has numerous subject matter experts who focus on chronic and interventional pain management, research, and patient safety.

The AANA appreciates the opportunity to comment on this guidance. We thank you for the opportunity to comment and further partner with the FDA. Should you have any questions regarding our comments or would like to speak further, please feel free to contact Shayne Hauglum, PhD, CRNA, the AANA Chief Science and Practice Officer at shauglum@aana.com.

Sincerely,



Jeffrey E. Molter, MBA, MSN, CRNA
AANA President

CC: William Bruce, AANA Chief Executive Officer
Shayne Hauglum, PhD, CRNA, AANA Chief Science and Practice Officer

² American Association of Nurse Anesthesiology. [Scope of Nurse Anesthesia Practice](#). Feb 2020.

³ American Association of Nurse Anesthesiology. [Chronic Pain Management Guidelines](#). Nov 2021.

⁴ International Association for the Study of Pain. Definitions of Chronic Pain Syndromes. <https://www.iasp-pain.org/advocacy/definitions-of-chronic-pain-syndromes/>. Accessed Oct 21, 2025.