

May 25, 2023

## Recent 2023 FDA Approvals

Jeanelle Jacobs



*Credit: Getty Images.*

The US Food and Drug Administration (FDA) approved drugs in April and May 2023 relevant to conditions often treated by nurse practitioners and PAs. Approvals include treatments for chronic migraine, type 1 diabetes, blood cancers, tardive dyskinesia and chorea associated with Huntington disease, vasomotor symptoms of menopause, pain and fever, and Fabry disease.

### **Caldolor® for Pain & Fever in Children**

Caldolor® (ibuprofen; Cumberland Pharmaceuticals) Injection was approved by the FDA for the treatment of pain and fever in pediatric patients 6 months of age and older. This is the first nonsteroidal anti-inflammatory drug (NSAID) approved for use in pediatric patients.

The approval was based on data from clinical trials that evaluated the safety and efficacy of this agent in hospitalized febrile children and children undergoing tonsillectomy surgery. A statistically significant greater reduction in temperature was seen in pediatric patients given Caldolor vs acetaminophen; 74% of patients treated with Caldolor became afebrile by the end of the first dosing interval.

The most common side effects reported in pediatric patients were infusion site pain, vomiting, nausea, anemia, and headache. Caldolor must be diluted before administration.

The drug is also approved for adults in the management of mild to moderate pain and moderate to severe pain as an adjunct to opioid analgesics, as well as for the reduction of fever.