Guidance for Development of Nonopioid Analgesics

The FDA recently issued a draft guidance for companies developing nonopioid analgesics for acute pain, such as from trauma or surgery, that lasts up to 30 days. Appropriately prescribed opioid analgesics play an important role in acute pain management, the FDA noted. However, even at prescribed doses, they pose a risk for misuse, abuse, or potentially fatal overdose, according to the agency.

"Opioid misuse and abuse remain a serious public health crisis facing the country," Patrizia Cavazzoni, MD, director of the FDA's Center for Drug Evaluation and Research, said in a statement. "Preventing new addiction through fostering the development of novel non-opioid analgesics is an important priority for the FDA."

A nonopioid analgesic for acute pain that eliminates or reduces the need for an opioid could greatly impact public health by mitigating the risks associated with opioid use, the FDA said.

The draft guidance describes the FDA's current thinking about 3 issues involved in nonopioid analgesic drug development for acute pain: the types of drug development programs that could provide data for an acute pain indication; possible labeling claims regarding the elimination or reduction of opioid use; and potential use of the FDA's expedited programs, which include the accelerated approval pathway.

The guidance, which isn't binding, was written in response to statutory requirements of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. A future guidance will address the management of chronic pain, the FDA said.

The FDA is accepting public comments on the draft guidance until April 11.

First Generic to Treat Dry Eye

The FDA recently approved the first generic formulation of cyclosporine ophthalmic emulsion (Restasis) to increase tear production for patients with a condition known as dry eye.

"Cyclosporine ophthalmic emulsion is an immunomodulator that helps increase tear production. The most common adverse effect reported in clinical trials of the brand name product was ocular burning. Other adverse effects in the eye included conjunctival hyperemia, which is dilation and redness of blood vessels; excessive watering; and blurred vision. Some drugs lack generic competition because of their complex active ingredient formulation or route of delivery," the FDA noted.

The agency said it is trying to encourage the development of complex generics through its Generic Drug User Fee Amendments (GDUFA) program.

The FDA began conducting research to support the development of bioequivalence recommendations for cyclosporine ophthalmic emulsion as part of its GDUFA Science and Research Program. In 2016, the FDA published a draft guidance specifically about cyclosporine ophthalmic emulsion; so far, the agency said, it has supported 16 research projects related to cyclosporine ophthalmic emulsion.

Another Step Toward Improving Nutrition by Reducing Sodium

The recent US Department of Agriculture (USDA) Food and Nutrition Service's final rule on school-based meals' transitional standards helps support the federal government's ongoing efforts to improve nutrition, reduce chronic disease, and help create a more healthful food supply, FDA officials said in a statement.

Toward that goal, the FDA released in October 2021 a guidance document establishing voluntary sodium reduction targets in processed, packaged, and prepared foods over the next 2.5 years. The USDA's rule for school meals notes that its transitional sodium standards align with the FDA's short-term voluntary sodium reduction targets, former Acting FDA Commissioner and current Principal Deputy Commissioner Janet Woodcock, MD, and Susan Mayne, PhD, director of the FDA's Center for Food Safety and Applied Nutrition, pointed out in their statement.

Although the weekly sodium limit for school breakfast and lunch will not change for the 2022-2023 school year, it will drop by 10% for the following school year, according to the USDA's final rule.

"While our nutrition work at the FDA is important, we recognize that we are just one part of the nutrition ecosystem tasked to help enable people to improve their diets," Woodcock and Mayne said.

The Dietary Guidelines for Americans, 2020-2025, advises that people aged 14 years or older limit their sodium consumption to 2300 mg/d. However, the average US sodium intake is approximately 3400 mg/d, according to the Dietary Guidelines.

More than 70% of total sodium intake is from what’s added during food manufacturing and commercial food preparation, according to the FDA. The agency’s guidance sets a goal of reducing average sodium intake to 3000 mg/d in 2.5 years. -- Rita Rubin, MA

Note: Source references are available through embedded hyperlinks in the article text online.