News From the Food and Drug Administration

Cardiac Ultrasound Uses Artificial Intelligence to Produce Images

The FDA has authorized the first cardiac ultrasound software using artificial intelligence to guide clinicians in capturing diagnostic-quality images of a patient's heart.

Called Caption Guidance, the software is indicated for use in adults undergoing 2-dimensional transthoracic echocardiography to obtain standard views of the heart from different angles.

FDA officials said the software was developed using machine learning to train it to differentiate between acceptable and unacceptable image quality. The software guides users on how to maneuver the ultrasound probe to acquire standard echocardiographic images and video clips of diagnostic quality. It automatically saves the best video clip from a particular view.

Robert Ochs, PhD, deputy director in the FDA's Office of In Vitro Diagnostics and Radiological Health, noted that health professionals who aren't experts in ultrasonography can still use the software. "This is especially important because it demonstrates the potential for artificial intelligence and machine learning technologies to increase access to safe and effective cardiac diagnostics that can be life-saving for patients," he said.

The FDA evaluated data from 2 independent studies in its review of the software. One study showed that 50 trained sonographers were able to capture diagnostic-quality images with and without the software. In the other study, 8 registered nurses who had no prior ultrasound experience were trained on the software and then asked to use it to capture standard echocardiographic images. Five cardiologists assessed the quality of the images and found them to be of diagnostic quality.

According to the manufacturer, Caption Health Inc of Brisbane, California, the software will initially be used in acute point-of-care settings including emergency departments, anesthesiology departments, and critical care units.

FDA Takes on Agricultural Biotech

A new pilot program from the FDA's Center for Veterinary Medicine is intended to facilitate the development of genetically altered animal products and clarify the regulatory process involved in bringing those products to market. The Veterinary Innovation Program covers "intentional genomic alterations in animals and animal cells, tissues, and cell- or tissue-based products seeking FDA approval."

FDA Commissioner Stephen Hahn, MD, said in a statement that genome editing is a groundbreaking technology that "has the potential to improve human and animal health, animal well-being and to enhance food production and quality." Maintaining standards of safety and effectiveness are paramount, he added.

Hahn's statement indicated that the FDA plans to launch a public education campaign to help consumers learn about agricultural biotechnology products. The agency also wants to partner with farmers, innovators, biotechnology companies, and research universities that are using techniques such as genome editing.

In a recent *Nature Biotechnology* article, FDA scientists reported on gene editing to introduce an allele into Holstein cattle to produce animals with no horns—a trait that protects their handlers and other animals from injury. However, an unintended consequence occurred. Along with the desired allele, which occurs naturally in some cattle, the edit introduced a DNA sequence not found in nature that contained antibiotic resistance markers.

In a companion article, Steven Solomon, DVM, MPH, director of the FDA's Center for Veterinary Medicine, emphasized that the genome edit his colleagues reported on "does not necessarily represent a safety concern in this instance."

But the study illustrates, Solomon wrote, "why it is necessary for there to be regulatory oversight of intentional genomic alterations in animals, even when the intended modification seeks to replicate a naturally occurring mutation."

Prescription Drugs Switched to OTC

Three prescription drugs—1 used to treat osteoarthritis pain and 2 for ocular conjunctivitis—have been approved for over-the-counter (OTC) sales. The drugs will no longer be available by prescription.

Diclofenac sodium topical gel, 1% is a nonsteroidal anti-inflammatory drug that will be sold as Voltaren Arthritis Pain. It was approved in 2007 to relieve osteoarthritis pain that responds to topical treatment, particularly in joints of the hands, knees, and feet. Diclofenac can cause a severe allergic reaction, especially in people who are allergic to aspirin.

Olopatadine HCl ophthalmic solution in both 0.1% and 0.2% concentrations will be available as Pataday Twice Daily Relief and Pataday Once Daily Relief, respectively. First approved in 2004, these drugs are mast cell stabilizers that prevent the release of histamine to prevent or control allergy symptoms. Each is used for temporary relief of red, itchy eyes due to pollen, ragweed, grass, or animal dander, which affect millions of people in the US.

Usually it's the prescription drug's manufacturer that initiates the process of changing the drug's status to OTC. To make the switch, manufacturers have to provide data showing that the drug is safe and effective when used according to the proposed label and that consumers can understand how to use it properly without a health professional's supervision.

Patients who use these drugs and have questions about the prescription-to-OTC change should talk with their health care professional. **– Rebecca Voelker, MSJ**

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