FDA Urged to Remove Boxed Warnings on Ultrasound Contrast Agents

August 31, 2020 03:20 PM Eastern Daylight Time

CHICAGO--(BUSINESS WIRE)--A grassroots medical society today urged the FDA to remove boxed warnings from ultrasound contrast agents (UCAs), citing compelling scientific data demonstrating their safety and life-saving potential.

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“Removing this 'black box' will help patients across America access safer, more reliable and more cost-effective diagnostic imaging, while speeding up the introduction of appropriate therapy and saving lives,” according to a Citizens Petition submitted to the FDA by the International Contrast Ultrasound Society (ICUS), a non-profit medical society that includes cardiologists, radiologists and other ultrasound imaging professionals.

The FDA will remove a “black box” when clinical evidence demonstrates that risks are less severe than previously thought, the ICUS Petition states.

“It is now abundantly clear that UCAs are extremely safe, and that they may save lives and lower overall diagnostic imaging costs,” said Dr. Michael Main, senior author of numerous safety studies that were cited in the Petition. Dr. Main is a Vice President of ICUS, co-executive medical director of Saint Luke’s Mid America Heart Institute, and a practicing cardiologist.

UCAs (sometimes also known as “ultrasound enhancing agents”) are radiation-free imaging agents comprised of biocompatible suspensions of tiny gas-filled microbubbles that are injected intravenously during an ultrasound exam. They produce high resolution ultrasound images that can dramatically improve the detection of heart disease, stratify risk of heart attack or stroke, and help identify, characterize and stage tumors of the liver, kidney, prostate, breast and other organ systems, according to the Petition.

UCAs present no known risk of kidney or liver damage, and are expelled from the body within minutes. In addition, patients do not require sedation during the contrast-enhanced ultrasound (CEUS) exam, the Petition added.

According to new studies and extensive clinical experience, “CEUS can help avoid unnecessary downstream tests, lower overall health care costs, reduce the length of hospital stays by speeding time to diagnosis and treatment, improve the efficiency of health care delivery, change patient outcomes and save lives,” according to the Petition.

“Extensive new scientific data convincingly show that UCAs are extremely safe and beneficial across a wide range of medical uses and patient populations,” according to Dr. Steven Feinstein, Co-President of ICUS. Dr. Feinstein is an expert in cardiac CEUS and professor of medicine at Rush University Medical Center in Chicago.

“The current labeling is outdated and may harm patients by unduly deterring the use of UCAs in patients who would benefit from an enhanced ultrasound scan,” Feinstein added.

The ICUS Petition cited an outpouring of support from other major ultrasound organizations and individual CEUS experts, who joined ICUS in acknowledging the favorable safety profile of UCAs and the risk that inappropriate labeling may unduly deter use and jeopardize patient care.

“CEUS is an exceedingly safe, low-cost and versatile imaging option that produces exquisite images in a variety of clinical settings,” said Dr. Stephanie Wilson, Co-President of ICUS. Dr. Wilson is an expert in abdominal CEUS and a professor of medicine at the University of Calgary in Canada.

CEUS is often comparable to CT and MR in its ability to characterize liver and kidney lesions, according to Dr. Edward Grant, treasurer of ICUS, past chair of the Department of Radiology at the University of Southern California Keck School of Medicine, and an expert in abdominal CEUS.

Three UCAs are currently approved for use in the United States -- Definity (Lantheus Medical Imaging), Lumason (Bracco) and Optison (GE Healthcare).

The FDA first mandated boxed warnings on UCA labels in 2007. Since then, the initial warnings and contra-indications have been reduced in response to a growing body of safety studies and expanding uses in adults and children.

“Since the FDA’s most recent and appropriate actions on UCA product labels, the body of relevant scientific literature has continued to mature and now convincingly shows that UCAs are among the safest diagnostic imaging products available,” according to the ICUS Petition.

“Removing this 'black box' will help patients across America access safer, more reliable and more cost-effective diagnostic imaging, while speeding up the introduction of appropriate therapy and saving lives. The public interest -- as well as the FDA's own standards -- demand nothing less,” the Petition concludes.

ABOUT ICUS:

The International Contrast Ultrasound Society (ICUS) is a grassroots, non-profit medical society dedicated to advancing the safe and appropriate use of contrast enhanced ultrasound (CEUS) to improve patient care. ICUS members include physicians, scientists, and other ultrasound imaging professionals in approximately 60 countries. For more information about ICUS, please visit www.icus-society.org.

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