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By Theresa Defino

FDA Issues Warning Letter to University of Kentucky Animal Researcher

Research conducted at the University of Kentucky (UK) on sheep involving a product called Novalung—which was approved by the Food and Drug Administration in February—violated numerous regulations, FDA recently warned a UK animal researcher. According to a March 26 warning letter to Professor of Surgery Joseph Zwischenberger that FDA posted on May 5, an inspection conducted from Nov. 4 to Nov. 21, 2019, found numerous violations dating back to 2016, including failure of both the study director and the quality assurance unit (QAU) to "fulfill [their] responsibilities." FDA said the director "did not ensure that raw data, specimens, and records were transferred to the archives for the nonclinical study; and did not ensure that the protocol was adequately followed"; and that incorrect and incomplete data about sheep involved in the study were reported. For example, one sheep had 15 "episodes of fever which were not documented in the final report," it said.

FDA did not include Zwischenberger's response to the inspection findings, but said he "concurred that the QAU failed to review the final study report to assure that it was accurate and indicated that your laboratory plans to establish a formal QAU with qualified QA staff, and that going forward, the final report and data audit for all GLP [good laboratory practice] studies will be completed in accordance with" regulations. He also told FDA that UK would establish a "GLP Oversight Committee no later than February 10, 2020 consisting of four members who will be responsible for advising and providing GLP assistance to any UK research laboratory intending to conduct a GLP study." FDA said Zwischenberger pledged to "prepare and complete an amended final report by May 31, 2020, which will be fully audited…and will include a signed GLP quality assurance statement specifying dates of inspections and findings reported to management and to the study director." FDA officials also recommended that he "conduct a systemic audit of your nonclinical lab procedures to ensure that you have adequately captured and resolved your laboratory's deviations. FDA cannot determine the adequacy of your response at this time since you have not provided all supporting documentation of your corrective and preventative actions," the agency concluded. It requested further responses within 15 days of Zwischenberger's receipt of the warning letter. Novalung is a "heart and lung support system for the treatment of acute or cardiopulmonary failure" and the first extracorporeal membrane oxygenation system "to be cleared for more than six hours of use as extracorporeal life support," Fresenius Medical Care North America announced Feb. 24.

Link to warning letter

Link to FDA approval announcement