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FDA Issues Warning Letter to U. of Michigan Professor

The Food and Drug Administration has accused a University of Michigan physician and professor of conducting research for more than three years after his approval from the agency expired, according to one of the first investigator warning letters FDA has published in many months. FDA's Feb. 27 letter to James Corbett, MD, follows a July 2019 inspection and seeks more information than it received from him at that time. According to his bio on the University of Michigan website, Corbett is a professor of medicine and specialist in myocardial perfusion imaging. The FDA letter does not specify what drug he was studying or the type of research. FDA said it terminated Corbett's investigational new drug (IND) application in June 2014 because he had failed to file a required annual report for at least two years. According to FDA, Corbett never obtained a new IND but continued enrolling 18 subjects and gave them a study drug up until January 2018. "Thus, subject safety and rights were compromised for a period of more than 3 years," the agency said based on its 2019 inspection. The agency also said Corbett had failed to notify the institutional review board that the IND was terminated and had enrolled a subject who should have been excluded based on a health condition.

FDA said Corbett had pledged to "discontinue conduct of all FDA-regulated research as either a sponsor or clinical investigator, effective immediately," and had explained that he "did not fully understand that an IND was necessary for a study using an FDA-approved drug as a 'stressor' in a normal healthy subject population. You stated that you further did not understand your responsibilities as a sponsor-investigator to maintain the IND throughout the conduct of this study," FDA told Corbett. "However, your response is inadequate because you failed to explain how you would conduct clinical investigations if you should undertake research in the future." It asked for a response to this question within 15 business days of Corbett's receipt of the letter.

[Link to warning letter](#)

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