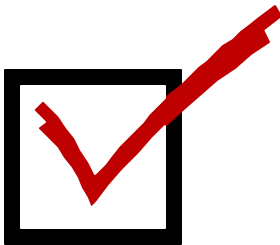

FDA Warning Letter Update

An FDA warning letter (OAI [Official Action Indicated]) was issued to the University of Arizona April 27, 2001 following an FDA audit in 2000. In essence, the citation was issued because a named study director and sponsor did not inform University Animal Care, The Office of the Vice President for Research or the campus Quality Assurance Unit that a GLP study was being conducted. A Form FDA-483 detailed the non-compliance items of the FDA regulations outlined in 21 CFR 58.

Subsequently, The Office of the Vice President for Research provided a point-by-point response to the audit results and initiated policies intended to assure such policy violations are not repeated. The FDA re-audited the University in 2002 and found no violations or an NAI (No action Indicated).

As is FDA's custom, the OAI warning letter will remain on the warning letter site, however the NAI is also clearly indicated, assuring private industry that The University laboratories are cleared to participate in projects in support of research or marketing permits regulated by the FDA.

To fulfill GLP standards and practices (as intended by 21 CFR 58), The University of Arizona appointed a Quality Assurance Officer [QAO] in June 2003 to report directly to The Director of Compliance, The Office of the Vice President for Research. All University generated GLP / IACUC protocols are now required to be reviewed by the Quality Assurance Officer and the Sponsored Projects routing sheet has a box to be checked for laboratories intending to undertake GLP studies.



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