From: OC GCP Questions
To: [redacted]
Subject: RE: FDA regulatory oversight - prospective and retrospective studies
Date: Friday, July 17, 2015 2:51:00 PM

Good afternoon,

FDA does not regulate the use of drugs in the course of medical practice and there are no FDA regulations that specifically speak to studies that involve chart reviews. If the results of such a study are for submission to FDA to support a change to conditions of approval for an approved medical product, e.g., to support a labeling change, it could be considered an FDA-regulated study regardless of whether the study design is prospective or retrospective. If the study will not support an application to FDA, as you describe, it is not likely to be an FDA-regulated study.

Your description of the study raises some questions about the proposed study, particularly the fact that the investigators may be prospectively studying the safety and effectiveness of an approved product. Consideration may need to be given as to whether the study is looking at the product's approved indication and how the investigators intend to use the data.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

From: [redacted]
Sent: Friday, July 17, 2015 10:24 AM
To: OC GCP Questions
Subject: FDA regulatory oversight - prospective and retrospective studies

Good morning,

I have a two-part question regarding FDA oversight over approved agents being investigated as they are used in the course of medical practice. For example, take a case where a study team would like to conduct a prospective observational study as well as a retrospective chart review of patients who will be receiving or have received a drug as part of standard of care. Their goals are to explore clinical safety and efficacy. The investigators have confirmed that they do not intend to submit data on subjects to the FDA as part of an application for research or a marketing permit. Are we correct in our understanding that the FDA regulations do not apply to this research? Is there a difference in

prospective and retrospective studies in which the drug under investigation is FDA approved and not administered for the purposes of the research?

Thank you in advance for your time,

[redacted]