From: OC GCP Questions
To: [redacted]
Subject: FDA Regulations for Approved Drug?
Date: Friday, October 16, 2015 6:28:04 AM

Good morning –

I am a bit confused as insulin is an approved drug used to treat Type 2 Diabetes so why is research involved? Does the study involve a new route of administration? Generally a clinical investigation is used to study safety and effectiveness/efficacy of an investigational product

21 CFR 312.3(b) states –
Clinical investigation means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

I think it is best to contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov or 301-796-3400 to obtain their advice on your question.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, October 15, 2015 1:32 PM
To: OC GCP Questions
Subject: FDA Regulations for Approved Drug?

Good afternoon!

I have a question about research involving FDA-approved drugs. I am the Regulatory Services Manager with the IRB at the [illegible], and we are currently reviewing a study which involves the infusion of insulin in subjects who have Type 2 Diabetes. The insulin is FDA-approved (Humulin®R).

My question is – would the FDA regulations for research with human subjects apply **even if** the drug is currently FDA approved? I know they definitely apply if the drug is currently investigational (IND), but I wanted to double-check if the FDA regulations for human subject research apply when the drug is currently FDA approved.

Thanks,
[redacted]