From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, September 27, 2006 3:26 PM
To: **[Redacted]**
Subject: RE: question re: marketed drug and 21 CFR 50.24

Dear Dr. **[Redacted]**:

It's in the regulations; see 21 CFR 312.2(b)(6): "A clinical investigation involving an exception from informed consent under 50.24 of this chapter is **NOT** exempt from the requirements of this part." [Emphasis added.]

I hope this answers your question.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: **[Redacted]**
Sent: Wednesday, September 27, 2006 12:16 PM
To: OC GCP Questions
Subject: question re: marketed drug and 21 CFR 50.24

Good afternoon,

I'm writing to request clarification about the FDA's guidance for ""Off-label" and Investigational Use of Marketed Drugs, Biologics and Medical Devices" (available at http://www.fda.gov/oc/ohrt/irbs/offlabel.html). The guidance specifically lists a study that invokes 21 CFR 50.24 (Exception from informed consent procedures for emergency research) as a study that must be conducted under an IND, even if the intervention is a marketed product.

However, the regulations at 21 CFR 312 list only the first five criteria, and do not appear to address studies conducted under 21 CFR 50.24.

Could you confirm whether studies conducted under 21 CFR 50.24 that use a marketed drug do require an IND/IDE submission or not?

Thank you,

[Redacted]