From: Melvin, Marsha N.
Sent: Tuesday, December 07, 2004 12:28 PM
To: [purged]
Cc: Hunsaker, Elisa; Hommel, Carolyn - OC
Subject: RE: Clinical Data Reporting Question

Dear Mr. [purged]

Your inquiry was forwarded to me for response.

You are correct that safety information should be reported for the emergency use cases. The information from the emergency use cases should be presented separate from the information from subjects under the protocol.

In general, effectiveness information would not need to be submitted on the emergency use cases because it is usually of limited value in determining effectiveness. Please be aware, however, that there may be some exceptions. For example, if an emergency use occurred because the patient was older than allowed in the study, (that is, the study excluded patients over a certain age), we may determine that the information is relevant and request effectiveness information on that patient.

Please note that you may consult with the review branch for your device regarding the specific information to include and its presentation.

Please let me know if I can be of further assistance.

Sincerely

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-----Original Message-----
From: [purged]
Sent: Monday, December 06, 2004 12:53 PM
To: gcquestions@oc.fda.gov
Subject: Clinical Data Reporting Question

Dear GCP staff:

Our client is completing an IDE study which will be submitted as a 510(k) application (FDA has already agreed to the submission format). In addition to the protocol patients (70 in total), a large number of emergency use patients were also treated by investigators participating in the IDE study (11 in total). All reporting requirements were satisfied for all emergency use patients (per 21 CFR 812). Our question pertains to how we report or utilize emergency-use data in the 510(k) submission. By definition, all emergency use patients did not satisfy the protocol inclusion/exclusion criteria, and thus are of limited value for demonstrating efficacy for the desired indication. However, we have details on all reported adverse events/effects. Would it be adequate for the pre-market submission to reference only "safety" variables (adverse events/effects) for the emergency use patients? What if any requirements exist to report emergency-use patient data in a pre-market submission (we can find none)?

Your assistance with this question would be greatly appreciated.

Please feel free to contact me by phone if I can provide any additional information [purged]

Thanks in advance,

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