From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, October 27, 2004 9:22 AM
To: [Redacted]
Subject: RE: DrugInfo Comment Form FDA/CIDER Site

Dear Ms. [Redacted],

As I mentioned in my earlier message, I am not aware of any FDA policies, guidances or regulations that suggest any particular threshold for the reporting (or notification) of adverse effects/experiences among any of the parties engaged in clinical research.

In fact, under 21 CFR 50.25(a)(2), the informed consent document must contain a description of any reasonably foreseeable risks or discomforts to the subject. Additionally, information about any new risks or side effects must be provided to the subject's as this new information may affect the subject's willing and continued participation in the study. (see comment # 31 in FDA preambles for 21 CFR 50 at http://www.fda.gov/oc/gcp/preambles/46fr.html)

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HF-34)
Office of Science and Health Coordination
Office of the Commissioner

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.

-----Original Message-----
From: [Redacted]
Sent: Tuesday, October 26, 2004 10:16 AM
To: OC GCP Questions
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Thank you for the response. I was thinking more in terms of not reporting to the sponsor or FDA, but what is required to be listed in the consent document.Of all the adverse events listed in an IB, is there a cut off for when they are not mentioned in an informed consent document.

At 08:47 AM 10/26/2004 -0400, you wrote:
>Dear Ms. [Redacted],
>
>Your message was referred to our office for direct reply. I am unaware of
>any FDA policy that suggests the reporting of adverse events the occur 2% or
>more of the time. Instead the regulations governing INDs require the

>sponsor to report to the FDA and all participating clinical investigators
>ANY adverse experience associated with the use of the drug that is both
>serious and unexpected [see 21 CFR 312.32(c)(1)(A)]. Also, under 21 CFR
>312.50, the sponsor must promptly inform the FDA and all participating
>clinical investigators of significant new adverse effects or risks with
>respect to the drug.
>
>A clinical investigator, through their signing of the Form FDA-1572, makes
>the commitment to report to the sponsor adverse experiences that occur in
>the course of the investigation in accordance with 21 CFR 312.64. The
>regulation, 21 CFR 312.64, requires the prompt reporting to the sponsor of
>any adverse effect that may reasonably be regarded as caused by, or probably
>caused, by the drug. If the adverse effect is alarming, the investigator is
>expected to report the adverse effect immediately. Under 21 CR 312.66, the
>clinical investigator must report to the IRB ..."all unanticipated problems
>involving risk to human subjects or others". [FDA interprets the phrase
>"unanticipated problems involving risk to human subjects or others" to mean
>an unexpected adverse experience that is not listed in the labeling for the
>test article. Such experience includes an event that may be symptomatically
>and pathophysiologically related to an event listed in the labeling but that
>differs from the event because of greater specificity or severity. The word
>"others" has previously been defined as persons who are participating in
>clinical trials under the same or similar protocols or who may be affected
>by products or procedures developed in those trials.]
>
>I hope this information is helpful to you. If you need any additional
>information, please feel free to contact our office directly.
>
>Sincerely,
>
>Patricia M. Beers Block
>Special Assistant to the Director
>Good Clinical Practice Programs (HF-34)
>Office of Science and Health Coordination
>Office of the Commissioner
>
>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.
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>-----Original Message-----
>From: CDER DRUGINFO
>Sent: Monday, October 18, 2004 11:21 AM
>To: OC GCP Questions
>Subject: FW: DrugInfo Comment Form FDA/CDER Site
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>
>-----Original Message-----
>From: [Redacted]

>Sent: Monday, October 18, 2004 10:47 AM
>To: druginfo@cder.fda.gov
>Subject: DrugInfo Comment Form FDA/CDER Site
>
>
>
>
> Name: [Redacted]
>
> E-Mail: [Redacted]
>
> Comments: When I was a [Redacted] and conducting
>clinical trials, I was told by several sponsors that there was a general
>policy of listing only the adverse events or risks that occur 2% of the time
>or greater. Now that I am working with the IRB, we are wondering where this
>policy or rule of thumb for industry has come from. I have searched the
>guidance documents somewhat and cannot find an origin for this policy. I am
>wondering if this is guicance the FDA has provided to industry during the
>IND process. IF at all possible, I would like to know the origin of this
>policy and whether or not this is supported by the FDA.