

Tory Bowes

From: Tory Bowes
Sent: Tuesday, June 04, 2002 2:21 PM
To: 'fdadockets@oc.fda.gov'
Subject: Response to Docket 01N-0233

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Response to docket
01N-0322, 6...

To Whom It May Concern:

I am attaching comments to Docket 01N-0233.

If you have any questions, please contact me directly.

Thank you.

Sincerely,
Victoria (Tory) Bowes
Associate Director, Regulatory Affairs
Northwest Biotherapeutics, Inc.
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01N-0322

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NASDAQ: NWBT

June 3, 2002

Docket Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 01N-0322
Institutional Review Boards: Requiring Sponsors and Investigators to Inform
IRBs of any Prior IRB Reviews

Dear Sir or Madam:

I am writing on behalf of a clinical trial sponsor, Northwest Biotherapeutics, Inc. (NWBT). We are involved in a multi-site Phase III clinical trial and are ready to initiate a multi-site Phase II study as well.

NWBT cautiously supports FDA's consideration of a proposed rule requiring sponsors and investigators to inform IRBs of any prior IRB reviews. From the sponsor's perspective, dissemination of previous IRB reviews will help alleviate the repetitive responses to IRB questions and concerns, as well as help to standardize the informed consent form. Currently, clinical sites involved in the same study may have vastly different consent forms. There should be a way to coordinate IRBs at each participating clinical site so that all research subjects will sign an informed consent that is closely related to the other informed consents at different sites.

While NWBT supports FDA's efforts to facilitate IRB review, we also recognize that there are a few caveats, mainly related to the practical nature of this rule. Is it realistic for sponsors of larger trials, such as those with 100 clinical sites, to disclose everything? Does this mean that the IRB for site number 100 would need to review 99 consent forms and IRB questions?

Perhaps one solution to this question would be to have sponsors summarize the activities with other clinical sites on a secured company web page. This could include questions that the sponsor has answered frequently for other IRBs, and could also include a list of which clinical sites have IRB approval.

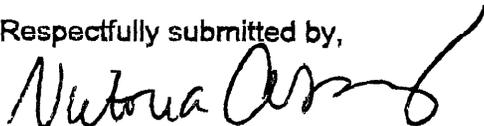
NWBT would also propose that FDA consider a working group on the issue of consistent guidelines for IRBs. It seems appropriate that a working group consisting of participants from FDA, clinical sites, and industry, as well as involving an organization such as the Food and Drug Law Institute (FDLI), could work together towards development and implementation of IRB regulations that would help each group. For example, FDA could require a standardized consent form where the format of the consent form is consistent,

making it easier to verify that the procedures and investigational drug or device is adequately explained to the subject. This type of standardized consent form would make it easier for FDA to audit these consents, and it would lessen the amount of time that IRBs use to review consent forms as well.

As mentioned earlier in this letter, NWBT supports FDA's efforts on determining the need for proposed rule making that requires sponsors and investigators to inform IRBs of any prior IRB reviews. This type of disclosure may expedite the initiation of a clinical trial that may benefit patients in the long run. However, it must be recognized that the burden of disclosing this information becomes an even bigger issue with studies that involve numerous clinical sites. Thus, NWBT supports, and would enthusiastically participate in, the formation of a working group. This working group could address IRB regulations, and how to make the entire process easier for IRBs, FDA, and industry.

Should you have any questions regarding these comments, or would like to discuss them further, please feel free to contact me at vbowes@nwbio.com.

Respectfully submitted by,



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