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May 1, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

**Subject: Response to Draft Guidance for Industry: IND Meetings for Human Drugs and
Biologics Chemistry Manufacturing and Controls Information Federal Register, Friday
February 4, 2000, Docket # 00D-0087**

To whom it may concern:

Novartis Pharmaceuticals Corporation has reviewed the above cited guidance and has the following comments:

Please add a clarification to the Introduction of the Guidance which states that pre-IND meetings prior to the initial IND submission should be arranged dependent upon the needs of the filing only. Meetings at this stage should not be considered as routinely necessary as those at later phases of development provided the project is generally straightforward at the initial stages, with few substantive issues to discuss. We wish to avoid the expectation that meetings are routinely necessary at the pre-IND submission stage.

This draft guidance offers up many possible scenarios that could be used for Pre-IND, End of Phase 2 and Pre NDA, CMC meetings. It would appear that the Agency is "requesting" industry to propose meetings with the FDA on possibly multiple occasions during the drug development process. What may occur as a result of this draft guidance is that industry will start to look for opportunities to meet with the Agency when a real need does not exist. We know that sponsors have sent meeting packages to the FDA only to be told that a meeting is not warranted.

As a result of the above-cited experiences, sponsors should do a "reality check" before they try to officially schedule a meeting. Perhaps some cautionary statements should be added to the guidance, which emphasises that a critical evaluation of the situation should be performed prior to an official meeting request (with the appropriate meeting package, which takes time and resources to assemble).

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Sometimes it is difficult, however, to do the "reality check" without FDA input. It would therefore be nice to have more opportunities for more informal discussions (telephone) between the Agency and sponsors. These discussions could lead a more open dialogue and therefore allow sponsors to more realistically prepare for meetings. Perhaps some of this could be built into the draft guidance.

Thank you for the opportunity to comment. If you have any questions, please contact me at (973) 781-6035.

Sincerely,

M. Hukkelhoven

Dr. Mathias Hukkelhoven
Vice President, Head US DRA
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