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NOVARTIS

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

Subject: Comments to Docket No. 2005D-0122, CDER 200497. Draft Guidance for Industry on Exploratory Investigational New Drugs Studies; Availability. Pages 19764-19765 [FR Doc. 0507485]

To whom it may concern:

Novartis is a world leader in the research and development of products to protect and improve health and well-being. As a global pharmaceutical corporation, Novartis is supportive of efforts to improve and to harmonize the technical requirements for registration of pharmaceutical products. We appreciate the opportunity to comment on this guidance in accordance with FDA's Good Guidance practices.

Novartis is generally in agreement with the Draft Guidance for Industry, Investigators, and Reviewers – Exploratory IND Studies, but would like to re-affirm the following:

General Comments

Care should be taken so as to separate out the requirements for drug substance and drug product. In addition, are the CMC requirements for exploratory INDs any less than those for Phase I INDs. Could you please indicate which Phase I IND CMC requirements are not needed for Exploratory INDs?

Specific Comments

1. Line 210 - Please eliminate the paragraph on this line as it pertains to GMP only.

2. Line 232 - The examples of grades of excipients given are all of US origin. The draft CHMP guidance for EU trials (up to and including Ph III) indicates that excipients complying with the pharmacopoeia of any ICH region would be found acceptable. A similar flexibility from the FDA, if permitted by existing legal instruments, would be highly appreciated.

3. Line 237 - Could this be read as suggesting that information (nature of dosage form and method of manufacture) must be given for the material administered in pre-clinical studies? It is assumed that information on pre-clinical material in the IND CMC section would be limited to D.S., for the purpose of comparing purity profiles and potential impurity presence. The introduction to this paragraph could be modified to avoid ambiguity.

4. Line 259 - For ophthalmic, inhalational, or parenteral dosage forms, results from sterility and pyrogenicity tests. This should be worded a bit more general, since inhalation products are usually not steril... e.g. results from sterility, **microbiological** and pyrogenicity tests **as adequate.**

These comments are being provided in duplicate in written form and electronically as directed in the Federal Register Notice.

Novartis appreciates the opportunity to submit these comments and looks forward to continuing to work collaboratively with the agency on this important Exploratory IND initiative.

Thank you for the opportunity to comment. If you have any questions, please contact me at (862) 778-7005 or at e-mail: robert.clark@novartis.com.

Sincerely,

Robert J. Clark
Director
Global Regulatory CMC

Submitted in duplicate