From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Thursday, May 19, 2005 2:24 PM
To: [purged]
Subject: RE: FDA acceptance of pre-clinical and clinical data from India

Dear [purged],

I apologize for my delayed response to your questions below, but I hope the information I now provide can still be of assistance to you. I'll try to answer each of your questions in turn.

Q. I was wondering if there is any guidance or standards regarding data that we might submit for the IND application.

Ans. The IND regulations contained in 21 CFR 312 identify all of the requirements necessary for an IND submission, including our requirements for acceptance of foreign data. These regulations are available on the internet at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312
If you are specifically interested in the general principles on IND submission you should refer to 312.22
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.22

Information on the content and format of an IND application is found in 312.23,
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.23

Q. What would the FDA require from us in terms of standards for ADMET studies conducted in India on animals as we
prepare to apply for an IND?

A. I'm not sure what the "T" stands for in the above acronym however, in general the IND application should contain: i) Pharmacology and drug disposition. A section describing the pharmacological effects and mechanism(s) of action of the drug in animals, and information on the absorption, distribution, metabolism, and excretion of the drug, if known.
and
(ii) Toxicology. (a) An integrated summary of the toxicological effects of the drug in animals and in vitro. Depending on the nature of the drug and the phase of the investigation, the description is to include the results of acute, subacute, and chronic toxicity tests; tests of the drug`s effects on reproduction and the developing fetus; any special toxicity test related to the drug`s particular mode of administration or conditions of use (e.g., inhalation,

dermal, or ocular toxicology); and any in vitro studies intended to evaluate drug toxicity.

Depending upon the nature of the animal studies FDA Good Laboratory Practice regulations found in 21 CFR 58 may be applicable. You can find these regulations at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=58

I hope this information is helpful.

Sincerely,

Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, 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: [purged]
Sent: Monday, April 11, 2005 6:23 PM
To: gcpquestions@oc.fda.gov
Subject: FDA acceptance of pre-clinical and clinical data from India

Dear Dr. David Lepay,
I am writing regarding the FDA's policy regarding accepting data for pre-clinical and clinical studies conducted in India for a biologic drug such as insulin. Based on my reading of the "FDA's Information Sheets for IRB's and Clinical Investigators" it seems like the key requirement for FDA acceptance of Indian data is the requirement that the studies be conducted under an approved IND and follow GCP.
I was wondering if there is any guidance or standards regarding data that we might submit for the IND application. What would the FDA require from us in terms of standards for ADMET studies conducted in India on animals as we prepare to apply for an IND?
I look forward to any guidance you can provide in this matter.

Sincerely,
[purged]