From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, September 17, 2004 10:18 AM
To: [Redacted]
Subject: RE: Medical screening period
Dear [Redacted],

The practices you describe in your first question are fine, provided informed consent is obtained prior to screening and prior to enrollment in a particular study.

In regard to your second question, the time period for medical screening of subjects for study enrollment, or any other time limits involved in a study, should be specified in that particular study protocol unless it is left to the professional judgment of the investigator.

I hope this information is helpful.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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: Saturday, September 04, 2004 8:58 AM
To: gcpquestions@oc.fda.gov
Subject: Medical screening period
Dear Sir

I have the following questions on medical screening of volunteers for bioequivalence studies as per ICH-GCP regulations.

Question 1

Currently many Phase I units generic advertising and screening procedures are performed in order to recruit subjects onto the unit's panel, the ethics committee has approved these generic processes including screening consent forms. Once individual studies are approved by the ethics committee eligible subjects are recruited from this panel, sign specifically informed consent and undergo any additional study specific screening tests.
CLARIFICATION is requested on WHETHER THE ABOVE PRACTICE IS OK.

Question 2

I would like to know the time period permitted for medical screening of subjects for study enrollment/admission to BE studies :
i.e. whether this should be within 15 days of admission or this period can be extended upto one/two months leaving it to medical judgement by the clinical investigator (actual regulatory valid period for medical screening for ECG, X-Ray, clinical chemistry, hematology and serology parameters.)

Thanks & regards
[Redacted]