From: OC GCP Questions
To: [redacted]
Subject: Informed consent- items other than study drug given to subject
Date: Wednesday, October 21, 2015 12:33:00 PM

Dear [redacted],
Responses are below your questions. I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Wednesday, October 21, 2015 1:33 AM
To: OC GCP Questions
Subject: Informed consent- items other than study drug given to subject

To FDA,

For a study in which the [redacted] product being investigated may have a side-effect of phototoxicity, the sponsor is providing subjects with sunscreen and lip balm with SPF.

Question #1: Should it be clearly stated in the protocol that the sunscreen and lip balm will be provided by the sponsor or is it OK for this detail to reside elsewhere (e.g. the [redacted])? This should be stated in the protocol. The SPF levels of both the sunscreen and lip balm should also be stated.

Question #2: Should the informed consent form specify that the sunscreen and lip balm will be provided by the sponsor or is it OK that the consent only instructs the subject to use sunscreen to protect exposed areas of the body? The informed consent form should specify that the sunscreen and lip balm will be provided by the sponsor. It may also be helpful to specify that subjects should use only these products according to the provided directions, unless there is a reaction to them (and what to do if they do have a reaction).

Thank you kindly for a prompt reply,
[redacted]