From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, April 02, 2003 11:29 AM
To: [Redacted]
Subject: RE: Waiver of parental consent

Dear Dr. [Redacted],

I apologize for the delay in this response. I hope this information is still helpful to you.

The regulations generally require that the investigator obtain informed consent from subjects. Investigators also may obtain informed consent from a legally authorized representative of the subject. FDA recognizes that a durable power of attorney might suffice as identifying a legally authorized representative under some state and local laws. For example, a subject might have designated an individual to provide consent with regard to health care decisions through a durable power of attorney and have specified that the individual also has the power to make decisions on entry into research. FDA defers to state and local laws regarding who is a legally authorized representative.

Therefore, the IRB should assure that the consent procedures comply with state and local laws, including assurance that the law applies to obtaining informed consent for subjects participating in research as well as for patients who require health care decisions. Since this investigation involves adolescents (i.e., minors), you may want to determine if there are any state laws that require parental consent for procedures involving minors.

[Redacted] Without knowing the ingredients, purpose or desired indications for this test article, it is difficult to say whether the product is a cosmetic or drug product. I might suggest you direct the Clinical Investigator to discuss the status of this product with FDA experts who can advise whether the test article might be the subject of an IND.

Advice concerning the need for an IND can be obtained from CDER's Drug Information Branch. Their phone number is 301-827-3453. They can also be contacted via email; their email account is druginfo@cder.fda.gov

Again, I apologize for the delay in this reply. Should you have any additional questions, please feel free to contact us again.

Most sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/FDA
301-827-3340

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 nor otherwise obligate or commit the agency to the views expressed. -

-----Original Message-----
From: [Redacted]

Sent: Tuesday, March 11, 2003 5:39 PM
To: gcpquestions@oc.fda.gov
Subject: Waiver of parental consent

To whom it may concern:

Our IRB is aware that the FDA regulations do not provide for waiver of parental consent for testing of pharmaceutical agents such as contraceptives in adolescent subjects.

One of our investigators wants to test [Redacted] in adolescent subjects. The research has to do with adolescent acceptance of such products. Is waiver of parental consent a possibility for such a study?

I thank you in advance for your response.

If I should address this question to a different site or office, please let me know.

[Redacted]