**From:** Toth-Allen, Jean
**Sent:** Friday, May 05, 2006 1:46 PM
**To:** [Redacted]
**Subject:** RE: special protocol assessment

Dear [Redacted]:

Thank you for your inquiry regarding special protocol assessment (SPA).

The guidance for industry in this regard is available at http://www.fda.gov/cber/gdlns/protocol.htm. This guidance was developed to implement sections of the Food and Drug Administration Modernization Act (FDAMA) of 1997 as well as the1997 reauthorization of the Prescription Drug User Fee Act (PUDFA) of 1992. Both of these acts require that FDA provide sponsors the opportunity for meetings and agreements to assist them in developing studies to support marketing of new drug products. The PUDFA requirements, applicable to human drug applications, apply to both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

Sponsors can request that FDA do a special protocol assessment to determine whether the protocol in question is adequate to meet the scientific and regulatory requirements which that particular protocol was written to meet. Three types of protocols related to PDUFA products are eligible for such an assessment: 1) animal carcinogenicity protocols, 2) final product stability protocols, and 3) clinical protocols for phase 3 clinical studies whose data will form the primary basis for an efficacy claim. (Clinical protocols for phase 3 studies can relate to efficacy claims that will be part of an original new drug application (NDA) or biologics license application (BLA) or that will be part of an efficacy supplement to an approved NDA or BLA.) Both CDER and CBER recommend that such an assessment request be made at least 90 days prior to the anticipated start of the study in question. (Special protocol assessment will **not** be provided after a study has begun.) Special protocol assessment is designed to evaluate individual protocols primarily in response to **specific questions** posed by the sponsor, including issues related to protocol design, study conduct and execution, data analysis, and implications for labeling. FDA's assessment will be based primarily on the questions posed by the sponsor, the underlying data, assumptions, information described by the sponsor, and relevant FDA policies and guidance documents. PUDFA goals are that comments from the review team be sent to the sponsor in a special protocol assessment letter within 45 calendar days of receipt of the request. However, FDA may request that an advisory committee meet to review the protocol or obtain advisory review from selected advisory committee members, special employees, or other consultants. Such review can delay a response. FDA will advise the sponsor of the expected date of the meeting or consultation and the reasons for seeking outside review. Once a special protocol assessment letter has been issued, FDA agrees that it will not later alter the perspective described in the letter regarding issues of design, execution, or analyses unless public health concerns unrecognized at the time of protocol assessment are evident.

The document found at the link provided above includes guidance regarding the timing of a special protocol assessment request, the format of the request, where to send the request, the content of a request, and the possible actions the agency can take with regard to such a request.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program

OSHC, Office of the Commissioner, US 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.

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**From:** [Redacted]
**Sent:** Tuesday, May 02, 2006 4:08 PM
**To:** OC GCP Questions
**Subject:** special protocol assessment

Having reviewed the FDA webpage on the special protocol assessment (SPA), and having asked to no avail several research offices at our university what it is and what is its purpose (expedited review or alteration in study design and size), could you please tell me what it is and what is its purpose. Thanks.

[Redacted]