OMB Control No.: 0910-xxxx
Expiration date: xx/xx/xxxx

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-xxxx. The time required to complete this information collection is estimated to average 10 minutes per response, including the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Sponsor Survey: Instrument

Instructions:

In completing this survey, please think about your recent Type [A/B/B EOC/C] meeting for IND [number]. All guidelines and requirements referenced in the questions pertain to:

Best Practices for Communication Between IND Sponsors and FDA During Drug Development Guidance for Industry and Review Staff (hereafter referred to as "communications guidance")

and

Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products (hereafter referred to as "meetings guidance").

FDA Guidances

1. For this meeting, the meetings guidance was helpful in understanding:	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Don't Know**
Requirements for the meeting request.	O	O	O	O	O	O
Requirements for the meeting package.	O	O	O	O	O	O
What to expect during the meeting.	O	O	O	O	O	O

2. Comments on the meeting process:

Before the Meeting

3. In preparing for this meeting, we found that:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know
The required meeting package format was effective for communicating our questions/issues to FDA.	O	O	O	O	O	O
FDA's preliminary comments were responsive to our questions/issues.	O	O	O	O	O	O
FDA's preliminary comments clearly distinguished between regulatory requirements and advice.	O	O	O	O	O	O
Where appropriate, FDA's preliminary comments directed us to specific regulations or guidance.	O	O	O	O	O	O

4. (Optional) Comments on communication processes and practices *before* the meeting:

The Meeting

5. From our perspective:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know
FDA staff who we requested, needed to answer our questions, were present.	O	O	O	O	O	O
FDA clearly distinguished between regulatory requirements and advice.	O	O	O	O	O	O
FDA directed us to specific regulations or guidance where appropriate.	O	O	O	O	O	O
This meeting was an effective means of addressing our	O	O	O	O	O	O

questions/issues.

6. (Optional) Comments on communication processes and practices *during* the meeting:

Other Feedback

7. What good practices contributed to a positive meeting planning and meeting experience?

8. What challenges hindered the efficiency or effectiveness of the meeting process and meeting?

9. What suggestions, if any, do you have for improving communication practices for IND meetings?

10. (Optional) Other comments related to the meeting: