Post-Action Interview: Scheduling Information

Keep this Scheduling Information sheet with interview information sheet until interview is complete. After interview, record interview response data in PETT and store this sheet in a secure location.

Interviewer: _____

NDA/BLA #: _____

Contact person: _____

Contact person title: _____

Contact person email: _____

Contact person phone: _____

Date(s) contacted: _____ (MM/DD/YYYY)

Agreed-upon date: _____ (MM/DD/YYYY)

Agreed-upon time: _____ (HH:MM AM/PM)

Agreed-upon location: _____

Interviewee(s):

1. Name _____
   Title/role _____
   Phone _____
   Email _____
2. Name _____
   Title/role _____
   Phone _____
   Email _____
3. Name _____
   Title/role _____
   Phone _____
   Email _____

Post-Action Interview: Interview Information

Complete this Interview Information sheet in advance.

Interviewer: _____

Note-taker: _____

NDA/BLA #: _____

Established name: _____

Sponsor: _____

Original application receipt date: _____ (MM/DD/YYYY)

Filed application submission date: _____ (MM/DD/YYYY)

Filing date: _____ (MM/DD/YYYY)

Review priority: Standard / Priority (circle one)

Interview date: _____ (MM/DD/YYYY)

Interview type: In-person / Phone (circle one)

Interviewee(s): FDA / Sponsor (circle one)

Role of interviewee #1 _____

Role of interviewee #2 _____

Role of interviewee #3 _____

Post-Action Interviews with Sponsor

Beginning the Interview

Thank you for taking the time to talk with us today. I am [name] and this is [name], from Eastern Research Group.

If face-to-face, shake hands.

If multiple interviewees are present and do not spontaneously introduce themselves, prompt:

And you are?

Pleasure to meet you.

Alternative if Sponsor(s) is/are known to interviewer: Good to see you.

As part of our independent assessment of FDA's program for enhanced review transparency and communication under PDUFA V, we would like to ask you about your experiences with the review process for NDA/BLA [application number], [established name].

The purpose of this interview is to obtain your opinions and feedback about review transparency and communication for this application under the PDUFA V NME Program. We are not evaluating your application for [established name] or the performance of any individual FDA staff members.

This interview should take about an hour to an hour and a half. I will ask questions, and [name(s)] will take notes. ERG will keep your identifying information confidential. We will share only anonymized results outside our internal project team. Here is the standard government statement about the voluntary nature of this information collection:

Public reporting burden for this collection of information is estimated to average 60-90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other suggestions for reducing this burden to ***Ila S. Mizrachi,*** *Office of Information Management, Food and Drug Administration, 1350 Picard Drive, PI50-400B, Rockville, MD 20850, 301-796-7726, Ila.Mizrachi@fda.hhs.gov. Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subjected to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.*

The OMB Control Number for this information collection is OMB Control Number 0910-New.

Do you have any questions before we start?

After any questions have been addressed, proceed to 'Conducting the Interview.'

Conducting the Interview

Please feel free to ask me to clarify if anything is unclear. To start, I'd like to ask you for your quick gut reaction to how key steps (e.g., pre-submission meeting, mid-cycle communication, late-cycle meeting) in the process contributed to the review of the application for [established name].

Q1. I am going to read a series of statements about steps in the NDA/BLA review process. For each statement, please tell me if you strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree. You can also say "Don't know" or "Not applicable".

Repeat response options after each statement (unless interviewee responds without prompt): "Do you strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree?"

As the interviewee responds, mark the appropriate cell to record the response.

Step in Review Process	Statement	Agreement Rating						
		Strongly disagree	Disagree	Neither agree nor	Agree	Strongly	Don't know	Not Applicable
Pre-submission meeting	The pre-submission meeting took place far enough in advance of application submission to allow for incorporation of FDA feedback in the NDA/BLA.							
	The pre-submission meeting was an effective forum for discussing questions and issues with FDA prior to submission.							
	The pre-submission meeting was attended by the appropriate FDA staff to allow sufficient discussion of questions and issues at the meeting.							
	The pre-submission meeting provided insight into FDA's preliminary stance on the need for REMS or other risk management actions based on the information provided to the agency to date.							
	The pre-submission meeting resulted in a clear and shared understanding of expectations regarding the content of the complete application prior to submission.							

Step in Review Process	Statement	Agreement Rating						
		Strongly disagree	Disagree	Neither agree nor	Agree	Strongly	Don't know	Not
	Discussion of the content of the complete application and delayed submission of minor components: • Allowed for planning of application-related activities prior to submission.							
	• Resulted in an earlier submission of the original application. (That is, without agreement on late components, you would have needed to delay the original submission.)							
	• Resulted in a later-than-planned submission of the original application.							
Day 74 letter	FDA's preliminary thinking on the need for an Advisory Committee meeting provided in the Day 74 letter was helpful for planning purposes.							
	The Day 74 letter provided transparent information about potential NDA/BLA review issues.							
Mid-cycle communication	The mid-cycle communication provided transparent information about: • The current status of the application.							
	• Significant issues identified by the review team.							
	• Major safety concerns identified thus far and preliminary thinking on risk management.							
	Information provided in the mid-cycle communication allowed for efficient: • Responses to information requests.							
	• Preparation of other items such as labeling language and PMC plans.							
Discipline Review letters	The Discipline Review letter(s) clearly delineated application deficiencies.							

Step in Review Process	Statement	Agreement Rating						
		Strongly disagree	Disagree	Neither agree nor	Agree	Strongly	Don't know	Not
	The Discipline Review letter(s) included a path forward to address the deficiencies communicated in the letter.							
	(*If applicable*) Receiving Discipline Review letters in advance of the late-cycle meeting allowed time to prepare for discussing the deficiencies at the late-cycle meeting.							
Late-cycle meeting	The late-cycle meeting provided transparent information about: • The current status of the application.							
	• Remaining application deficiencies.							
	• FDA's assessment of the need for REMS or other risk management actions.							
	The late-cycle meeting was an effective forum for: • Discussing questions and issues with FDA.							
	• Discussing FDA information needs.							
	• Planning for the remainder of the review process.							
	• Discussing the Advisory Committee meeting.							
	The late-cycle meeting was held far enough in advance of the Advisory Committee meeting to allow sufficient time to prepare.							
Process as a whole	I felt well-informed about the status of my NDA/BLA as a result of interactions with FDA during the agency's review of the application.							
	I was not surprised by the action letter I received.							
	Interactions with FDA allowed sufficient planning for manufacturing scale-up and launch activities (approvals) or resubmission of the application (for CRs).							

Now I'd like to ask you about any experiences that you would consider either good practices or challenges during the review of the application for [established name].

Q2. What types of practices did you find helpful in the review?

Probe about elements of the Program

Probe for insights on how/why specific practices were helpful.

Q3. What types of challenges did you encounter in the review?

Probe about elements of the Program

Probe for insights on how/why specific aspects were challenging.

Q4. Can you comment on your experience in the Program with respect to the transparency, efficiency, and predictability of the review process?

If applicant has regulatory experience with FDA, probe for insights about how this experience compared to previous experiences in terms of transparency, efficiency, and predictability of the review process.

Q5. Have you identified any "lessons learned" that might help you or FDA with future application reviews?

Q6. Is there anything else you'd like to add about your review experience with [established name]?

Closing the Interview

Thank you very much for taking the time to talk with us. Your feedback is helpful in giving us a sense of how application review processes under the PDUFA V Program for enhanced review transparency and communication are working from a real-world perspective. Thanks again.