

26-Jul-2005 03:13 PM

Message Size: 6.9 KB

To [REDACTED]  
cc [REDACTED]  
bcc [REDACTED]

Subject: Fw: PIND 73,061 BG00012 Meeting Request

[REDACTED]  
Please file with BG12 MS IND.



"Wheelous, Teresa A"  
<WHEELOUST@cdcr.fda.gov  
>

07/26/2005 03:09 PM

To [REDACTED]  
cc [REDACTED]

Subject: PIND 73,061 BG00012 Meeting Request

[REDACTED]  
Please refer to your correspondence dated July 8, 2005 and received July 11, 2005, requesting a type B Pre-IND meeting.

Based on the statement of purpose, objectives, and proposed agenda, we consider the meeting a type B meeting as described in our guidance for industry titled *Formal Meetings with Sponsors and Applicants for PDUFA Products* (February 2000). The meeting is scheduled for:

Date: September 1, 2005

Time: 2 PM - 3 PM

Location: 1451 Rockville Pike, Conference Room E, Rockville, MD 20852

CDER participants: To be determined

Please have all attendees bring photo identification and allow 15-30 minutes to complete security clearance. If there are additional attendees, email that information to me at [wheeloust@cdcr.fda.gov](mailto:wheeloust@cdcr.fda.gov) so that I can give the security staff time to prepare temporary badges in advance. Upon arrival at FDA, give the guards either of the following numbers to request an escort to the conference room: Teresa Wheelous or the division secretary at 301-594-2850.

Additionally, please email your discussion questions to me in MS WORD format.

Provide the background information for this meeting (one copy to the IND and 9 desk copies to me) at least one month prior to the meeting. If the materials presented in the information package are inadequate to justify holding a meeting, or if we do not receive the package by

August 2, 2005, we may cancel or reschedule the meeting.

*CDR Teresa Wheelous, R. Ph.*  
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*Division of Neurology Products*  
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