Biogen Idec CONFIDENTIAL

AGENCY TELEPHONE CONTACT REPORT

PRODUCT: BG00012	Application #: IND 73,061		
DATE/TIME OF CONTACT 27 October 2006, 02 November 2006 and 03 November 2006	INCOMING: ⊠	OUTGOING:	
AGENCY REPRESENTATIVE(S): James Reese, Project Manager 301-796-1136			
Biogen Idec PARTICIPANT(S): Tammy Sarnelli			
SUBJECT: Receipt of the Request for Special 301 and 302	l Protocol Assessments (Si	PA) for Studies	

On October 27, 2006 I left Jim Reese a voicemail to notify him that Biogen Idec submitted 2 Phase 3 SPAs to the Agency for review. I also requested confirmation that the 45-day review period would end on December 11, 2006. I followed the voicemail message with an email as well.

On November 2, 2006, Jim Reese sent an email stating that he had received the 302 SPA (Serial No. 0013) but was searching for the 301 SPA (Serial No. 0012). He stated that he would let me know if he could not find it, but he was certain he would.

On November 3, 2006, Jim Reese sent an email stating that the goal date for review is December 11, 2006.

ACTION(S) REQUIRED			
FOLLOW-UP ACTIVITY	RESPONSIBILITY	DATE DUE	
N/A	N/A	N/A	
cc: Regulatory CMC, Regulatory Cambridge, Regulatory UK, BG12 Program Team			