

12/21/2017

ATTACHMENT – BsUFA Survey

Instructions: Below is a list of your active pre-IND/INDs in the Biosimilar Biological Product Development (BPD) program. Please review the list and answer all questions in this survey. Your responses to these questions are vital to assist the Food and Drug Administration in determining the fees for fiscal year 20XX (October 1, 20XX to September 30, 20XX).

Firm Name:

BPD Program		
1.	For the active pre-IND/INDs listed above, do you anticipate discontinuing participation in the BPD program by August 1 of this year?	<input type="checkbox"/> No <input type="checkbox"/> Yes (please list IND numbers)
2.	Do you anticipate reactivating a pre-IND/IND that was discontinued from the BPD program?	<input type="checkbox"/> No <input type="checkbox"/> Yes (please list IND numbers)
3.	How many new biosimilar biological products do you anticipate will enter the BPD program in the current fiscal year (October 1, 20XX – September 30, 20XX)?	
4.	How many new biosimilar biological products do you anticipate will enter the BPD program in the next fiscal year (October 1, 20XX – September 30, 20XX)?	

351(k) Submissions		
1.	Of the active pre-IND/INDs listed above, do you plan to submit a new 351(k) application in the current fiscal year ? If yes, please list the IND number(s) and the anticipated month and year (MM/YYYY) of submission in the right-hand column.	<input type="checkbox"/> No <input type="checkbox"/> Yes
2.	Of the active pre-IND/INDs listed above, do you plan to submit a new 351(k) application in the next fiscal year ? If yes, please list the IND number(s) and the anticipated month and year (MM/YYYY) of submission in the right-hand column.	<input type="checkbox"/> No <input type="checkbox"/> Yes
3.	Do you plan to resubmit a 351(k) application that was Refuse To File or Withdrawn before filing? If yes, please list the BLA number(s) and the anticipated month and year (MM/YYYY) of re-submission in the right-hand column.	<input type="checkbox"/> No <input type="checkbox"/> Yes
4.	Do you plan to resubmit a 351(k) application that received a Complete Response? If yes, please list the BLA number(s) and the anticipated month and year (MM/YYYY) of re-submission in the right-hand column.	<input type="checkbox"/> No <input type="checkbox"/> Yes
5.	Do you plan to submit an interchangeability supplement? If yes, please list the BLA number(s) and the anticipated month and year (MM/YYYY) of re-submission in the right column.	<input type="checkbox"/> No <input type="checkbox"/> Yes
6.	Do you plan to submit a new strength supplement to an approved application? If yes, please list the BLA number(s) anticipated month and year (MM/YYYY), and number of new strengths in the right-hand column.	<input type="checkbox"/> No <input type="checkbox"/> Yes

Approved Biosimilar Biological Products		
1.	Are you planning to discontinue marketing of an approved biosimilar biological product by September 30, 20XX?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A
2.	If yes to the question above, please list the products and the strengths.	