12/21/2017

Biosimilar User Fee Cover Sheet - Form FDA 3792

OMB Control No. 0910-0718

JUSTIFICATION MEMORANDUM FOR 83-C CHANGE REQUEST

The Food and Drug Administration is submitting this change request (83-C) regarding OMB Control No. 0910-0718, Biosimilar User Fee Cover Sheet for implementation by April 2018.

The Biosimilar User Fee Act of 2012 (BsUFA) authorized FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development (BPD) including certain applications and supplements for approval, certain products, and certain establishments where biosimilar biological products are manufactured.

The BSUFA program was reauthorized for an additional 5 years in August 2017 (BsUFA II). It requires FDA to set and publish appropriate biosimilar user fees annually[1] and to assess and collect those user fees for certain BPD meetings concerning biosimilars, for investigational new drug applications (INDs) intended to support a biosimilar biological product application, and for biosimilar biological product marketing applications and supplements. BsUFA II has specific requirements for the amount of fees collected in any given fiscal year. If FDA collects too much revenue (e.g., fees are set too high or more BsUFA II elements than anticipated are received, then FDA would potentially have to issue refunds (a significant increase in the cost to administer the program). If FDA collects too little revenue (e.g., fees are set too low, or number of fees assessed are fewer than estimated) then the Agency will have to absorb that deficit and FDA loses available funds for the program. Consequently, as close to actual and accurate information is required for setting appropriate BsUFA II fees.

Although the BsUFA II program is similar to the agency's Prescription Drug User Fee program, it is much smaller in number of participants and much less mature. Available information under BsUFA does not provide adequate historical data on which to base reasonable estimates of incoming submissions and BsUFA II participation. Under BsUFA, OMB previously approved an annual one question e-mail survey of BPD developers of anticipated submissions of biosimilar applications in the upcoming fiscal year. However, it has been determined that asking respondents in the BPD program of only their anticipated submission of marketing applications is insufficient to accurately determine upcoming fiscal year fees for all parts of the BsUFA II program. FDA believes that amending the survey of BPD sponsors and collecting expanded data with a few additional questions will resolve FDA's current difficulty for determining BsUFA II fees, and will enable FDA to more efficiently administer the BPD program under BsUFA II.

To accomplish this goal for the fiscal year 2019 review cycle and to publish the BsUFA II fees by August, FDA proposes to administer the attached survey (and clarifying questions if required) via

[1] Some of the BsUFA II fees are due on October 1, the first day of the fiscal year, so FDA publishes the fees by August prior to the start of the fiscal year.

e-mail, on an annual basis in April,[2] to all biosimilar product developers (Currently, there are 35 participants). The expanded survey (including what was previously approved) should take no more than 1 hour to complete.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Total Annual Burden (hours)
Fee Determination Survey	35	60	35 hours

[2] PRA-0910-0718 expires 12/2018. That collection, including this additional survey information, is currently in the comment and renewal process for OMB approval.

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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?	☐No ☐Yes *(please list IND numbers)*
2.	Do you anticipate reactivating a pre-IND/IND that was discontinued from the BPD program?	☐No ☐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.	☐No ☐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.	☐No ☐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.	☐No ☐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.	☐No ☐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.	☐No ☐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.	☐No ☐Yes

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