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 (we) is submitting this nonmaterial/non-substantive change request (83-C) regarding OMB Control No. 0910-0718, Biosimilar User Fee Cover Sheet.

The Biosimilar User Fee Act of 2012 (BsUFA) authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development including certain applications and supplements for approval, certain products and certain establishments where biosimilar biological products are manufactured. FDA's BsUFA program requires FDA to set appropriate biosimilar user fees annually, 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.

To improve the program, we are requesting to ask via e-mail, on an annual basis, product developers who submit FDA Form 3792 the following question: "*For each active BPD program, does the sponsor anticipate submitting a 351(k) application in the next fiscal year (Yes/No)?*" Each respondent would be instructed to click "*Reply*" on the incoming email from FDA, choose "*Yes*" or "*No*," and click "*Send*" back to FDA.

Although the BsUFA program is similar to the agency's PDUFA program, it is much smaller and much less mature, and it does not provide historical data with which we might improve our estimates. Asking respondents in the BPD program of their anticipated submission of marketing applications would benefit FDA in setting BsUFA fees more accurately and enable us to more efficiently administer BPD programs.