"Guidance to Industry: User Fee Waivers, Reductions, and Refunds for Drug and Biological Products"

(OMB Control Number 0910-0693)

CHANGE REQUEST (83-C)

Date: March 23, 2015

In brief, we are proposing a non-substantive change to the estimated burden to include burden hours that have been previously approved for the Small Business Administration (SBA) under OMB control number 3245-0101, for requests of information from applicants who have submitted pending small business waiver requests to FDA for fees for human drug applications. By way of background, Section 736(d)(1)(D) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs the Secretary to waive certain fees for small businesses named as applicants in a human drug application. The guidance, among other things, outlines the process in which SBA would work with FDA to help determine whether an applicant meets the criteria for being a small business. The guidance states that SBA may contact the applicant directly in order to request certain types of information regarding its size status, and that the applicant should not send this information directly to FDA.

The supporting statement for 0910-0693 states the following:

The FDA works with the Small Business Administration (SBA), which makes the determinations on whether the applicant is a small business for purposes of user fee waivers. SBA asks the applicant to submit certain information. That submission of information to SBA is already approved by OMB under OMB control number 3245-0101.

However, in November 2014, SBA informed FDA that it would no longer conduct size determinations for small business user fee waivers for FDA. As a result, FDA has had to develop a process for conducting its own size determinations for small business fee waivers for human drug applications. As part of this process, FDA plans to send a letter to applicants who currently have pending small business waiver requests, and ask them to submit their supporting documentation directly to FDA instead of SBA. The burden on applicants would not increase; rather, we estimate that it will decrease from the 4 hours estimated by SBA on its Form 355, Application for Small Business Size Determination (OMB Control No. 3245-0101), to 2 hours, because we are asking that applicants submit fewer supporting documents to FDA than they would have otherwise submitted to SBA.

Because FDA is now conducting these size determinations for applicants who request a small business waiver for human drug applications, SBA can amend 3245-0101 to reflect the reduction in SBA's collection hours. We understand that SBA plans to submit a revised burden estimate to

3245-0101 which will take into account the fact that SBA is no longer conducting size determinations for FDA.

There are currently 19 small business waiver requests that are pending review. FDA will be unable to evaluate these requests until it receives this supporting documentation from applicants. Many of these applicants are waiting to learn if their waiver requests are granted before submitting human drug applications, because the fee that would be waived is significant ($2.3 million for a human drug application submitted in FY 2015). Any additional delay could deter or prevent applicants from submitting applications, delaying or preventing market entry of new drug products.

In sum, we are proposing to add burden hours that have been previously approved for SBA under control number 3245-0101, for requests of information from applicants who have submitted pending small business waiver requests to FDA for fees for human drug applications . Furthermore, we estimate that the burden will decrease from 4 hours to 2 hours because we are asking that applicants submit fewer supporting documents to FDA than they would have otherwise submitted to SBA.