U.S. Food and Drug Administration

Expedited Programs for Serious Conditions - Drugs and Biologics;
Guidance for Industry

OMB Control No. 0910-0765

Non-substantive Change Request:

FDA is requesting a non-substantive change to OMB Control No. 0910-0765, which supports the above-captioned agency guidance document. The guidance describes FDA policies and procedures related to the following expedited review programs: *Fast Track Designation*; *Priority Review Designation Requests*; *Breakthrough Designation Requests*; and *Accelerated Approval*. In the Federal Register of November 17, 2017 (82 FR 54385), we announced the availability of a draft guidance entitled "*Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry*" ("RMAT draft guidance"). The RMAT draft guidance explains an additional program referred to as "regenerative medicine advanced therapy" (RMAT) designation and provides our current thinking on the expedited development and review of these products.

Similar to the information collection found in the guidance document currently included in the approved collection package, the information collection found in the RMAT draft guidance document also supports the implementation of section 506(g) of the Federal Food, Drug, and Cosmetic Act. Section 506(g) authorizes the agency to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to address an unmet medical need. Both guidance documents also include recommendations and instruction on information needed by FDA to make a determine as to whether a particular product satisfies certain designation criteria. While the RMAT draft guidance discusses an additional expedited program available to sponsors, we do not believe it introduces ***new*** information collection. Rather, it informs sponsors of an additional alternative by which certain products may be evaluated for a specified designation request. A sponsor may apply for and receive more than one designation for a given product. At the same time, sponsors need to apply for each designation separately. Also, the information a sponsor must submit in order to apply for RMAT designation is substantially the same information that a sponsor must submit in order to apply for the other designation requests, namely a request for the designation as well as a premeeting package with supporting material.

As discussed above, we believe the information collection elements associated with RMAT designations are reflected under OMB Control No. 0910-0765; however, we have considered that additional respondents may be included to reflect those preparing and submitting RMAT designation requests. Based on a review of agency data, we estimate that 35 applicants will prepare and submit RMAT designation requests, and that each submission will require approximately 60 hours to develop and submit to FDA as part of the application. We also estimate that 10 premeeting packages will be prepared and that it will require approximately 100 hours per request. These estimates are reflected in the following table:

Table 1-- Estimated Annual Reporting Burden

Expedited programs for serious conditions – Drugs and Biologics	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
RMAT Designation Requests	35	1	35	60	2,100
Premeeting Packages	10	1	10	100	1,000
TOTAL					3,100

We intend to finalize the RMAT draft guidance, and we believe it is appropriate to consolidate the RMAT designation requests and premeeting packages with those approved under OMB Control No. 0910-0765. We also propose to retitle the information collection: "Expedited Programs for Serious Conditions - Drugs and Biologics" to reflect that it includes more than a single FDA guidance document.

Dated: September 2018