Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics

0910-NEW

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Priority Review Designation Request: Section C of Appendix 1 of the guidance describes that a sponsor may expressly request priority review of an application. Under the Prescription Drug User Fee Act (PDUFA) of 1992, the Food and Drug Administration (FDA) agreed to specific goals for improving the drug review time and created a two-tiered system of review times – standard review and priority review. A priority review means that the time it takes FDA to review a marketing application is reduced.

Breakthrough Therapy Designation Request: Section B of Appendix 1 of the guidance describes the process for sponsors to request breakthrough therapy designation. Section 506(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by section 902 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 provides for the designation of a drug as a breakthrough therapy if it meets the qualifying criteria. Section 902 of FDASIA instructs FDA to take actions appropriate to expedite the development and review of a breakthrough therapy.

Promotional Materials for Accelerated Approval Under Part 314: Section VII.D.1 of the guidance describes section 506(c)(2)(B) of the FD&C Act and FDA's accelerated approval regulations (21 CFR 314.550 and 601.45). These provisions authorize FDA to require sponsors to submit copies of all promotional materials to the

Agency for consideration prior to their dissemination. Currently, FDA has OMB approval for the submission of copies of all promotional materials under part 601 (OMB control number 0910-0338) but does not have approval for the submission of copies of all promotional materials for accelerated approval under 21 CFR 314.550.

2. Purpose and Use of the Information Collection

The information collection for the priority review designation request provides a means for sponsors to expressly request priority review of an application to shorten the amount of time for FDA review of a marketing application from 10 months to 6 months. The guidance describes that FDA determines whether an application qualifies for priority review for every application, however, an applicant may expressly request priority review. The information will be used by FDA to assess whether drug products meet the qualifying criteria for priority review designation.

The information collection for the breakthrough therapy designation request provides a means for sponsors to request breakthrough therapy designation to expedite drug development and review. The information will be used by FDA to assess whether drug products meet the qualifying criteria for breakthrough therapy designation.

The information collection for promotional materials for accelerated approval under part 314 provides a means for sponsors to submit copies of all promotional materials to the Agency prior to their dissemination, as required by 21 CFR 314.550. The information will be used by FDA to assess whether the material complies with FDA requirements.

3. Use of Improved Information Technology and Burden Reduction

Sponsors may use electronic means to submit a priority review designation request and a breakthrough therapy designation request when practicable.[1] Approximately 95% of priority review and 80% of breakthrough therapy designation requests are submitted electronically. FDA is not able to accept promotional materials electronically at this time. FDA is taking steps to accept promotional materials for accelerated approval electronically in the future. FDA is not aware of any other improved technology to reduce the burden.

One of FDA's continuing objectives is to improve the speed and quality of its review and approval programs. To make the approval process more efficient for industry and FDA, CBER (Center for Biologics Evaluation and Research) and CDER (Center for Drug Evaluation and Research) are utilizing electronic information systems technology.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requires the submission of a request for designation as a breakthrough therapy, the optional submission of a request for priority review, and submission of copies of all promotional materials for accelerated approval under 21 CFR 314.550. This information is not available from any other source. This information collection does not duplicate any other information collection. Currently, FDA has OMB approval for the submission of copies of all promotional material materials under part 601 (OMB control number 0910-0338) but does not have approval for the submission of copies of all promotional materials under part 314.

[1] See Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf

5. Impact on Small Businesses or Other Small Entities

Approximately 10% of respondents for priority review designation request, breakthrough therapy designation requests, and promotional material for accelerated approval under 21 CFR 314.550 are small businesses. FDA's authority and responsibility to ensure the safe use of investigational drugs and biologics applies to small as well as to large businesses involved in sponsoring investigational studies. FDA believes that its responsibility requires the equal application of the regulations to all businesses. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. In CDER, the Office of Communications includes a small business staff.

6. Consequences of Collecting the Information Less Frequently

The guidance describes that FDA determines whether an application qualifies for priority review for every application, however, an applicant may expressly request priority review. A sponsor submits a priority review designation request once. The guidance describes a sponsor submits of a breakthrough therapy designation request once. Less frequent collection of this information would not provide the necessary information needed by FDA to make the appropriate determination. The guidance summarizes and references the requirements for the submission of promotional material for accelerated approval under 21 CFR 314.550. Because a sponsor submits promotional material for accelerated approval under 21 CFR 314.550, prior to dissemination, the frequency of the collection varies depending on the sponsor’s promotional activities and is expected to occur occasionally. Less frequent collection of this information would not allow FDA to review the material prior to dissemination.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

An applicant may be required to submit to FDA proprietary trade secrets or other confidential information when submitting a license, application or supplement. FDA has instituted security measures to protect confidential information received from manufacturers and will, to the extent permitted by law, protect this information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the FEDERAL REGISTER of June 26, 2013 (78 FR 39349), a 60-day notice was published for public comment on this information collection. FDA received 26 comments. However, these comments did not address the information collection.

9. Explanation of Any Payment or Gift to Respondents

No remuneration has been provided.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 314.430 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under section 310(j) of the FD&C Act.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA currently has approval for the information collection required under 21 CFR 202.1, certain parts of 21 CFR 314, and 21 CFR 601, and sections 506(b)(1), 735, and 736 of the FD&C Act (21 U.S.C. 356(b)(1), 379g, and 379h) (OMB control numbers 0910-0686, 0910-0001, 0910-0338, 0910-0389 and 0910-0297).

Specifically, FDA currently has OMB approval for the information collection required under 21 CFR 202.1 (OMB control number 0910-0686), which describe the requirements and standards for drug advertisements. FDA currently has OMB approval for the collection of certain information required under 21 CFR part 314 (OMB control number 0910-0001), which describes the requirements imposed on sponsors who apply for approval of a new drug application (NDA), including accelerated approval, or abbreviated new drug application (ANDA) in order to market or to continue to market a drug. FDA currently has OMB approval for the information collection required under 21 CFR part 601 (OMB control number 0910-0338), which includes submission of copies of all promotional materials. FDA currently has OMB approval for information collection required under section 506(b)(1) of the Food, Drug, and Cosmetic Act (FD&C Act) (OMB control number 0910-0389) which authorizes FDA 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. FDA currently has OMB approval for information collection required under sections 735 and 736 of the FD&C Act (OMB control number 0910-0297), which grants FDA the authority to assess and collect user fees for certain drug and biologics license applications and supplements.

FDA requests OMB approval of the information collection provisions contained in the above-titled Guidance for Industry that provides a single resource for information on FDA's policies and procedures related to the following expedited programs for serious conditions: (1) fast track designation; (2) breakthrough therapy designation; (3) accelerated approval; and (4) priority review designation.

The collection of information associated with this draft guidance that is not currently approved under OMB control numbers 0910-0686, 0910-0001, 0910-0338, 0910-0389, and 0910-0297 follows.

We estimate that approximately 47 sponsors will prepare and submit approximately 1 priority review designation submission in accordance with the guidance and that the added burden for each submission will be approximately 30 hours to develop and submit to FDA as part of the application (totaling 1,410 hours). We estimate that approximately 24 sponsors will prepare approximately 1 breakthrough therapy designation submission in accordance with the guidance and that the added burden for each submission will be approximately 70 hours to prepare and submit (totaling 1,680 hours). We estimate that approximately 20 sponsors will submit promotional materials for accelerated approval 7 times annually in accordance with § 314.550 and that the burden for each submission will be approximately 120 hours (a total of 16,800 hours).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Guidance on expedited programs	Number of respondents	Number of responses per respondent	Total annual response	Average burden per response	Total hours
Priority Review Designation Request……	47	1	47	30	1,410
Breakthrough Therapy Designation Request…….	24	1	24[2]	70	1,680
Promotional Materials for Accelerated Approval Under § 314.550……	20	7	140	120	16,800
Total……	…….	……..	……	……	19,890

12b. Annualized Cost Burden Estimate

The cost estimates for priority review designation requests and breakthrough therapy designation requests is based on an average pharmaceutical industry loaded wage rate of $75.00 per hour for developing and submitting the request. Multiplied times the total hour burden estimated above, the total cost burden to respondents for priority review designation requests is $105,750. Multiplied times the total hour burden estimated above, the total cost burden to respondents for breakthrough therapy designation requests is $126,000.

The cost estimate for promotional materials for accelerated approval under §314.550 is based on an average pharmaceutical industry loaded wage rate of $75.00 per hour for submitting the promotional material. Multiplied times the total burden estimated above, the total cost burden to respondents is $1,260,000.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

[2] Based on more recent data, the estimate may be closer to 30 annual responses.

14. Annualized Cost to the Federal Government

FDA staff review the priority review and breakthrough therapy designation requests submitted by sponsors to determine if the qualifying criteria described in the guidance are met to grant the designation. The grade level of the staff who perform these reviews ranges from a GS-12 to a GS-15 and it takes approximately 10 hours and 81 hours cumulative (i.e., combined hours of all disciplines involved) to complete a priority review designation request and breakthrough therapy designation request, respectively. The annual cost to the Federal government is approximately $50,137.25 for the review of priority review designation requests and $207,376.20 for the review of breakthrough therapy designation requests, depending on how many priority review and breakthrough therapy designation requests are received for review and the grade level of the staff providing review.

FDA staff review the promotional materials for accelerated approval under 21 CFR 314.550 prior to their dissemination. The grade level of the staff who perform these reviews ranges from a GS-13 to a GS-14 and it takes 40-120 hours cumulative (i.e., combined hours of all disciplines involved) to complete a review. The annual cost to the Federal government is approximately $1,181,376 depending on how many submissions are received for review and the grade level of the staff providing review.

Therefore, the total annualized cost to the Federal government is $1,438,889.45.

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt the display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.