Guidance for Industry on Controlled Correspondence Related to Generic Drug Development

0910-[NEW]

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This ICR request provides FDA guidance on the process by which generic drug manufacturers and related industry can submit controlled correspondence to the Food and Drug Administation requesting information related to generic drug development. FDA is issuing this guidance as part of the Agency's implementation of the Generic Drug User Fee Amendments of 2012 (Public Law 112-133, Title III), commonly referred to as GDUFA. (There is no CFR citation for GDUFA.) Under GDUFA, FDA has agreed to specific program enhancements and performance goals, as set forth in the GDUFA Commitment Letter that accompanies the legislation. One of the performance goals applies to controlled correspondence related to generic drug development. This guidance provides detail and recommendations concerning what inquiries FDA considers to be controlled correspondence, what information requestors can include in a controlled correspondence, and what information FDA will provide in response to a controlled correspondence.

To facilitate FDA's prompt consideration of the controlled correspondence and prompt response thereto, and to assist in meeting the prescribed time frames, FDA recommends including the following information in the controlled correspondence inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) an email address; (3) an FDA-assigned control number and submission date of any previous related correspondence, if applicable; (4) the relevant reference listed drug, as applicable, including the application number, proprietary (brand)

name, manufacturer, active ingredient, dosage form, and strength(s); (5) a concise statement of the inquiry; (6) a recommendation of the appropriate FDA review discipline; and (7) relevant prior research and supporting materials.

2. Purposes and Use of the Information Collection

FDA is required to respond to questions submitted as controlled correspondence within prescribed timeframes as established under GDUFA and is committed to honoring these obligations. FDA will use the requested information to efficiently process and analyze inquiries related to generic drug development and promptly respond. Immediate identification of the requested information will allow FDA to focus its resources on a resolution of the inquiry as opposed to expending resources gathering this information at various stages in the analysis of the inquiry. Respondents will include members of the private sector. Specifically, respondents will be generic drug manufacturers and related industry (e.g., contract research organizations conducting bioanalytical or bioequivalence clinical trials) or their representatives.

3. Use of Improved Technology and Burden Reduction

Consistent with the agreement from industry described in the GDUFA Commitment Letter, requestors seeking FDA's response to a controlled correspondence by the goal dates articulated in the GDUFA Commitment Letter should submit the correspondence via email to GenericDrugs@fda.hhs.gov. As email submissions are highly encouraged and are the only variety that will receive a GDUFA goal date, the vast majority of controlled correspondence submissions have been submitted by email. FDA estimates that 99% of the respondents will use electronic means in order to receive the benefit of a goal date, as articulated in the GDUFA Commitment Letter. FDA is currently developing fillable, signable, and fileable controlled correspondence forms.

4. Efforts to Identify Duplication and Use of Similar Information

The information collection requested under this guidance does not duplicate any other information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection requested under this guidance will have no impact on small businesses.

6. Consequences of Collecting the Information Less Frequently

The information collection requested under this guidance is only requested at times respondents wish to submit a controlled correspondence. As described earlier, FDA will use the requested information to efficiently process and analyze the controlled correspondence inquiry and promptly respond. Immediate identification of the requested information will allow FDA to focus its resources on a resolution of the inquiry as opposed to expending resources gathering this information at various stages in the analysis of the inquiry. FDA finds that the information collection requested is critical to FDA achieving goal dates established under GDUFA. There are no legal obstacles to reduce the burden.

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

There are no special circumstances for this collection of 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), FDA published a 60-day notice requesting public comment on the proposed collection of information in the FEDERAL REGISTER of 08/27/2014 (79 FR 51180). We received several comments pertaining to the scope of controlled correspondence. We summarize the comments and provide our response below:

(Comment 1) Several comments expressed concern related to three types of requests that FDA proposed to exclude from the definition of controlled correspondence. The three exclusions are: (1)

requests for recommendations on the appropriate design of bioequivalence (BE) studies for a specific drug product (BE guidance requests), (2) requests for review of BE clinical protocols (clinical protocol requests), and (3) requests for meetings to discuss generic drug development prior to ANDA submission (pre-ANDA meeting requests).

(Response) FDA has not changed its policy regarding its consideration of requests for bioequivalence guidance, clinical protocol reviews, and pre-ANDA meetings. FDA will consider them promptly upon their electronic submission and will respond as expeditiously as practicable. Although the guidance states that these requests are not considered controlled correspondence submissions, requests for BE guidance and pre-ANDA meetings are included in the 1,020 total annual responses estimated in Table 1 because these requests will utilize the same information collection pathway as a request that is considered controlled correspondence. For reasons described in the draft guidance, however, controlled correspondence GDUFA metrics will not apply to FDA's responses to the three excluded requests.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention of providing any payment or gift to respondents under this guidance.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under this guidance is protected under 21 CFR 314.430 and 21 CFR part 20. The information collected will be maintained in FDA's electronic generic drug review platform for ANDAs, which is not public, and thus shares the same protections accorded ANDAs.

11. Justification for Sensitive Questions

The information collection requested does not include questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Provided below is an estimate of the annual reporting burden for controlled correspondence submissions under this guidance.

12 a. Annualized Hour Burden Estimate

FDA estimates approximately 217 generic drug manufacturers and related industry (e.g., contract research organizations conducting bioanalytical or bioequivalence clinical trials) or their representatives will each submit an average of 4.7 inquiries annually, for a total of 1,020 inquiries [1,020 ÷ 217 = 4.7]. Information submitted with each inquiry varies widely in content, depending on the complexity of the request. Inquiries that are defined as controlled correspondence (i.e., inquiries that request information on a specific element of generic drug product development) may range from a simple inquiry on generic drug labeling to a more complex inquiry requesting a formulation assessment for a specific proposed generic drug product. Preparing and submitting such inquiries can take 1 to 10 burden hours, respectively.

Because the content of inquiries considered controlled correspondence is widely varied, we are providing an average burden hour for each inquiry. We estimate it will take an average of 5 hours per inquiry for industry to gather necessary information, prepare the request, and submit the request to FDA. As a result, we estimate that it will take an average of 5,100 total hours annually for industry to prepare and submit inquiries considered controlled correspondence. Although the guidance states that certain requests, i.e., requests for bioequivalence guidance and pre-ANDA meetings, are not considered controlled correspondence submissions, they are included in the 1,020 total annual responses estimated in Table 1 because these requests will use the same information collection pathway as a request that is considered controlled correspondence.

There is no annual recordkeeping or third-party disclosure burden associated with this collection of information.

Table 1. Estimated Annual Reporting Burden					
Submission of controlled correspondence	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Generic drug manufacturers, related industry and their representatives	217	4.7	1,020	5	5,100

12 b. Annualized Cost Burden Estimate

There are no capital costs or operating and maintenance costs associated with this collection of information.

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

There are no other costs associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA estimates that there will be no additional costs associated with the receipt/review by FDA of the information submitted under this guidance.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There is no anticipated publication or manipulation of the information collection. FDA will prepare internal reports tabulating the controlled correspondence request type to facilitate tracking.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.