4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1592]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Controlled Correspondence Related to Generic Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0797. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Controlled Correspondence Related to Generic Drug Development

OMB Control Number 0910-0797--Extension

This information collection supports the above captioned Agency guidance. FDA has agreed to specific program enhancements and performance goals specified in the Generic Drug User Fee Reauthorization (GDUFA II) Commitment Letter. One of the performance goals applies to controlled correspondence related to generic drug development. The GDUFA II Commitment Letter includes details on FDA's commitment to respond to questions submitted as controlled correspondence within certain timeframes. To support these program goals, we have developed the guidance entitled "Controlled Correspondence Related to Generic Drug Development." The guidance document is intended to facilitate FDA's prompt consideration of controlled correspondence and to assist in meeting the prescribed timeframes by providing procedural recommendations to include the following information in the inquiry: (1) name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number and submission date of any previous, related controlled correspondence that was accepted for substantial review and response, if any, as well as a copy of that previous controlled correspondence and FDA's response, if any; (4) the relevant reference listed drug(s), as applicable, including the application number, proprietary (brand) name, manufacturer, active ingredient, dosage form, and strength(s); (5) a statement that the controlled correspondence is related to a potential abbreviated new drug application (ANDA) submission to the Office of Generic Drugs and the ANDA number, if

applicable; (6) a concise statement of the inquiry; (7) a recommendation of the appropriate FDA review discipline; and (8) relevant prior research and supporting materials.

The GDUFA II Commitment Letter also includes details on FDA's commitment to respond to requests to clarify ambiguities in FDA's controlled correspondence response within certain timeframes. To facilitate FDA's prompt consideration of the request and to assist in meeting the prescribed timeframes, the guidance document recommends including the following information in the inquiry: (1) name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number, submission date of the controlled correspondence on which the requestor is seeking clarification, a copy of that previous controlled correspondence, and FDA's response to the controlled correspondence; and (4) the clarifying questions and the corresponding section(s) of FDA's controlled correspondence response on which the requestor is seeking clarification.

In the *Federal Register* of May 22, 2018, (83 FR 23692), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

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 representatives	390	3.8	1,496	5	7,480

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

This is the first extension of the information collection. We base our estimate on a review of Agency data of Fiscal Year submissions for 2014, 2015, and 2016, which reflects an increase in submissions that we attribute to an increase in generic drug development. Accordingly, we estimate 390 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 3.8 inquiries annually for a total of 1,496 inquiries [1,496 ÷ 390 = 3.8]. Information submitted with each inquiry varies widely in content, depending on the complexity of the request. Inquiries that are defined as controlled correspondence may range from a simple inquiry on generic drug labeling to a more complex inquiry for a formulation assessment for a specific proposed generic drug product. As a result, these inquiries can vary between 1 and 10 burden hours.

Because the content of inquiries considered controlled correspondence is widely varied, we are providing an average burden hour for each inquiry. We estimate that 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 7,480 hours annually for industry to prepare and submit inquiries considered controlled correspondence.

Dated: August 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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