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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1167]

Draft Guidance for Industry on Controlled Correspondence Related to Generic Drug Development; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Controlled Correspondence Related to Generic Drug Development." The guidance document provides information regarding the process by which human generic drug manufacturers and related industry can submit correspondence to FDA requesting information on generic drug development. This guidance also describes FDA's process for providing communications related to such correspondence.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance and the collection of information proposed in the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Maryll Toufanian, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1682, Silver Spring, MD 20993-0002, 240-402-7944, Maryll.Toufanian@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Controlled Correspondence Related to Generic Drug Development." On July 9, 2012, the Generic Drug User Fee Amendments of 2012 (GDUFA) were signed into law by the President to speed the delivery of safe and effective generic drugs to the public and to reduce costs to industry. Under GDUFA, FDA agreed to certain obligations as laid out in the GDUFA Commitment Letter that accompanies the legislation (Ref. 1). Among these obligations is FDA's commitment to performance metrics for the response to controlled correspondence for fiscal years (FYs) 2015 through 2017. For example, FDA has committed to respond to 90 percent of controlled correspondence within 2 months from the date of submission in Year 5 of the program, which begins on October 1, 2016.

The GDUFA Commitment Letter described controlled correspondence as follows: "FDA's Office of Generic Drugs provides assistance to pharmaceutical firms and related industry regarding a variety of questions posed as 'controlled documents.' See [http://www.fda.gov/AboutFDA/CentersOffices/officeofmedicalproductsandtobacco/CDER/ucm120610.htm (Ref. 2)]. Controlled correspondence does not include citizen petitions, petitions for reconsideration, or requests for stay." The draft guidance is intended to further refine this description to best support the aims of the identified in the GDUFA Commitment Letter of ensuring the safety of generic drug products; enhancing access by expediting the availability of these products; and enhancing transparency by, among other things, improving FDA's communications and feedback with industry in order to expedite product access. In addition, this guidance provides detail and recommendations concerning what inquiries FDA considers as controlled correspondence for the purposes of meeting the Agency's GDUFA commitment, what information requestors can include in a controlled correspondence to facilitate FDA's consideration of and response to a controlled correspondence, and what information FDA will provide in its communications to entities that have submitted a controlled correspondence.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on controlled correspondence related to generic drug development. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection are given under this section with an estimate of the reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Controlled Correspondence Related to Generic Drug Development

Description: Under GDUFA, FDA has agreed to specific program enhancements and performance goals specified in the GDUFA Commitment Letter. One of the performance goals applies to controlled correspondence related to generic drug development. The Commitment Letter includes details on FDA's commitment to respond to questions submitted as controlled correspondence within certain time frames. To facilitate FDA's prompt consideration of the controlled correspondence and response, and to assist in meeting the prescribed time frames, FDA recommends including the following information in the 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.

The following information is based on inquiries considered controlled correspondence and submitted to FDA for FYs 2011, 2012, and 2013. FDA estimates approximately 217 generic drug manufacturers and related industry (e.g., contract research organizations conducting bioanalytical or bioequivalence clinical trials) or their representatives would 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 for a formulation assessment for a specific proposed generic drug product. As a result, these inquiries can vary between 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 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 5,100 total hours annually for industry to prepare and submit inquiries considered controlled correspondence.

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
Manufacturers, Related Industry, and Representatives	217	4.7	1,020	5	5,100

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

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

V. References

1. Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA Commitment Letter) for fiscal years 2013 through 2017, available at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf).

2. Id. at p. 15. The Web page quoted in the controlled correspondence definition has been updated as the link provided in the GDUFA Commitment Letter is no longer accessible.

Dated: August 22, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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