standard cost (rounded to the nearest thousand dollars) of $5,122,000 for a NME NDA and $4,090,000 for a BLA. Based on these standard costs, the total cost to review the 53 applications in these two categories in FY 2013 (31 NME NDAs with clinical data and 22 BLAs) was $248,762,000. (Note: These numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.) Twenty of these applications (12 NDAs and 8 BLAs) received priority review, which would mean that the remaining 33 received standard reviews. Because a priority review compresses a review that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject. In the article ''Developing Drugs for Developing Countries,'' published in ''Health Affairs'', Volume 25, Number 2, in 2006, the comparison of historical average review times by David B. Ridley, Henry G. Grabowski, and Jeffrey L. Moe supports a priority review multiplier in the range of 1.48 to 2.35. The multiplier derived by FDA falls well below the midpoint of this range. Using FY 2013 figures, the costs of a priority and standard review are estimated using the following formula:

$(20\ \alpha \times 1.67) + (33\ \alpha) = \$248{,}762{,}000$

Where ''α'' is the cost of a standard review and ''α times 1.67'' is the cost of a priority review. Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be $3,746,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $6,256,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or $2,510,000, represents the incremental cost of conducting a priority review rather than a standard review.

For FY 2015 fee, FDA will need to adjust the FY 2013 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2014, to adjust the FY 2013 amount for cost increases in FY 2014. That adjustment, published in the **Federal Register** on August 1, 2014 (see 79 FR 44807 at 44809), setting FY 2015 PDUFA fees, is 2.0813 percent for the most recent year, not compounded. Increasing the FY 2013 incremental priority review cost of $2,510,000 by 2.0813 percent results in an estimated cost of $2,562,000 (rounded to the nearest thousand dollars). This is the priority review user fee amount for FY 2015 that must be submitted with a priority review voucher in FY 2015, in addition to any PDUFA fee that is required for such an application.

III. Priority Review Fee Schedule for FY 2015

The fee rate for FY 2015 is set out in table 1:

TABLE 1—TROPICAL DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2015

Fee category	Fee rate for FY 2015
Application submitted with a priority review voucher in addition to the normal PDUFA Fee	$2,562,000

IV. Implementation of Priority Review Fee

Under section 524(c)(4)(A) of the FD&C Act, the priority review user fee is due upon submission of a human drug application for which the priority review voucher is used. Section 524(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act and FDA may not collect priority review voucher fees prior to a relevant appropriation for fees for that FY. Beginning with FDA's appropriation for FY 2009, the annual appropriation language states specifically that ''priority review user fees authorized by 21 U.S.C. 360n (section 524 of the FD&C Act) may be credited to this account, to remain available until expended.'' (Pub. L. 111–8, Section 5, Division A, Title VI).

The priority review fee established in the new fee schedule must be paid for any application that is received on or after October 1, 2014, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. The user fee identification (ID) number should be included on the check, followed by the words ''Priority Review.'' Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only.) The FDA post office box number (P.O. Box 979107) must be written on the check. The tax identification number of FDA is 53–0196965.

Wire transfer payments may also be used. Please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993–0002.

Dated: August 22, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–20360 Filed 8–26–14; 8:45 am]

BILLING CODE 4164–01–P

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 October 27, 2014. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by October 27, 2014.

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	Number of respondents	Number 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.

[FR Doc. 2014–20359 Filed 8–26–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1082]

Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices.'' This guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of highly multiplexed microbiological/medical countermeasure in vitro nucleic acid-based diagnostic devices (HMMDs) intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Hobson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5560, Silver Spring, MD 20993–0002, 301–796–5892.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of HMMDs intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture. For the purposes of this guidance document, the multiplex level that is used to define HMMDs is the capability to detect ≥20 different organisms/targets, in a single reaction, using a nucleic acid-based technology and involves testing multiple targets through a common process of specimen preparation, amplification and/or detection, and result interpretation. HMMDs are used