DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1167]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 August 3, 2015.

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 title. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 on Controlled Correspondence Related to Generic Drug Development OMB Control Number 0910–NEW

In the **Federal Register** of August 27, 2014 (79 FR 51180), FDA announced the availability of a draft guidance for industry entitled ''Controlled Correspondence Related to Generic Drug Development.'' The draft guidance provided information regarding the process by which human generic drug manufacturers and related industry can submit correspondence to FDA requesting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 described FDA's process for providing communications related to such correspondence.

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).

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 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.

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.

In the **Federal Register** of August 27, 2014 (79 FR 51180), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received several comments pertaining to the scope of controlled correspondence. We summarize the comments and provide our response below:

(Comment) 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.

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.

Description of Respondents: Respondents are human generic drug manufacturers and related industry.

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.

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: June 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2008]

Unapproved and Misbranded Otic Prescription Drug Products; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intention to take enforcement action against unapproved and misbranded otic drug products labeled for prescription use and containing benzocaine; benzocaine and antipyrine; benzocaine, antipyrine, and zinc acetate; benzocaine, chloroxylenol, and hydrocortisone; chloroxylenol and pramoxine; or chloroxylenol, pramoxine, and hydrocortisone; and against persons who manufacture or cause the manufacture or distribution of such products in interstate commerce. These unapproved and misbranded prescription drug products are marketed without evidence of safety and effectiveness; may present safety concerns; and pose a direct challenge to the new drug approval system and, in some cases, the over-the-counter (OTC) drug monograph system.

DATES: This notice is effective July 2, 2015. For information about enforcement dates, see **SUPPLEMENTARY INFORMATION**, section IV.

ADDRESSES: For all communications in response to this notice, identify with Docket No. FDA–2015–N–2008 and direct to the appropriate office listed in this **ADDRESSES** section as follows:

Applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(b)): Division of Anesthesia, Analgesia, and Addiction Products (for drug products with analgesic and anti-inflammatory indications), or Division of Anti-Infective Drug Products (for drug products with anti-infective indications), Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002.

Applications under section 505(j) of the FD&C Act: Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Silver Spring, MD 20993–0002.

All other communications about this action should be directed to: Kathleen Joyce, Division of Prescription Drugs, Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5236, Silver Spring, MD 20993–0002; 301–796–3329 or email: *Kathleen.Joyce@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Kathleen Joyce, Division of Prescription Drugs, Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5236, Silver Spring, MD 20993–0002; 301–796–3329 or email: *Kathleen.Joyce@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to take enforcement action against certain unapproved and misbranded otic drug products labeled for prescription use. These marketed unapproved and misbranded otic drug products are labeled for, among other things, the temporary relief of pain associated with ear infections or inflammation, including acute otitis media (middle ear infection), otitis media with effusion (fluid in the ear, but without infection), and acute otitis externa (infection in the outer ear or ''swimmer's ear''). Other indications for these unapproved drug products include anti-infective and anti-inflammatory claims, as well as claims for the removal of cerumen (earwax).

This notice covers the following marketed unapproved prescription otic drug products: (1) Single-ingredient otic drug products containing benzocaine; (2) fixed-dose combination otic drug products containing benzocaine and antipyrine; (3) fixed-dose combination otic drug products containing benzocaine, antipyrine, and zinc