PONDIMIN (fenfluramine HCl) tablets, 20 mg, and PONDEREX (fenfluramine HCl) capsules, 20 mg, were the subject of NDA 16–618, held by Wyeth Pharmaceuticals, and were initially approved on June 14, 1973. PONDIMIN (fenfluramine HCl) sustained release tablets, 60 mg, was the subject of NDA 16–618, held by Wyeth Pharmaceuticals, and was initially approved in 1982. PONDIMIN and PONDEREX were indicated for treatment of obesity.

In 1997, FDA asked that PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules be withdrawn from the market after receiving new evidence that the products were associated with valvular heart disease (September 15, 1997, FDA Announces Withdrawal Fenfluramine and Dexfenfluramine (Fen-Phen), available on the Internet at *http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm179871.htm;* see FDA November 1997 Fen-Phen Safety Update Information, available on the Internet at *http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm072820.htm*). Wyeth Pharmaceuticals subsequently discontinued marketing these products. On October 8, 1998, FDA issued a Notice of Proposed Rulemaking proposing to include certain drug products on a list of drug products that had been withdrawn or removed from the market because such drugs products or components of such drug products had been found to be unsafe or not effective, and which could not be compounded under section 503A of the FD&C Act (63 FR 54082). FDA identified in that notice ''all drug products containing fenfluramine hydrochloride.'' The notice also noted that fenfluramine HCl tablets, formerly marketed as PONDIMIN tablets, were associated with valvular heart disease, and the manufacturer voluntarily withdrew the drug from the market. This proposed rule was finalized in 64 FR 10944 (March 8, 1999), 21 CFR 216.24.

In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA issued a notice that it was withdrawing approval of 92 new drug applications and 49 abbreviated new drug applications, including PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules, under section 505(e) of the FD&C Act. Consistent with § 314.161 and its prior rulemaking on compounded drug products under 21 CFR 216.24, FDA has determined that PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules were withdrawn from sale for reasons of safety or effectiveness. This determination is consistent with FDA's prior request and Wyeth Pharmaceutical's withdrawal of PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules from the market for reasons of safety or effectiveness. The Agency previously removed PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules from the list of drug products published in the Orange Book. FDA will not accept or approve any ANDAs that refer to these drug products.

Dated: September 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24619 Filed 9–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1167]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a 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: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Maryll Toufanian, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 75, Rm. 1684, Silver Spring, MD 20993–0002, 240–402–7944, *Maryll.Toufanian@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a 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.

Under the provisions of the Generic Drug User Fee Amendments of 2012 (GDUFA), FDA agreed to certain obligations as laid out in the Generic Drug User Fee Act Program Performance Goals and Procedures for fiscal years 2013 through 2017 (the GDUFA Commitment Letter) that accompanies the legislation (Ref. 1). Among those obligations is FDA's commitment to performance metrics for its responses to controlled correspondence for fiscal years 2015 through 2017.

This guidance finalizes the draft guidance announced in the **Federal Register** on August 27, 2014 (79 FR 51180). The Agency considered comments on the draft guidance while finalizing this guidance. Generally, we revised the draft guidance to provide clarifying and explanatory information that will assist human generic drug manufacturers and related industry as they submit controlled correspondence to FDA. Changes from the draft guidance include a description of a process to submit information to update the Agency's Inactive Ingredient Database and a description of enhanced communication to requestors regarding the status of their controlled correspondence.

Two comment threads on the draft guidance benefit from additional

discussion here. Specifically, FDA received numerous comments regarding two categories of requests that FDA proposed in the draft guidance to exclude from the controlled correspondence process. First, FDA received comments requesting that the Agency refrain from excluding requests for product-specific guidance on demonstrating bioequivalence. FDA declines to revise the guidance in this fashion. As set out in the draft guidance, the short timeframe contemplated for the controlled correspondence responses is inconsistent with the well-established process for issuing product-specific recommendations described in the guidance for industry on ''Bioequivalence Recommendations for Specific Products (June 2010)'', as well as with the principles in the GDUFA Commitment Letter regarding the Regulatory Science Initiative. Rather than incorporating such guidance development into the controlled correspondence process, FDA's Office of Generic Drugs (OGD) is developing a separate process for product-specific guidance development.

This approach is being managed by the Division of Therapeutic Performance (DTP) within OGD's Office of Research and Standards, involves representatives from numerous divisions and offices within OGD, and provides for timely posting of product-specific recommendations to facilitate generic drug development. Requests for product-specific guidance development received through the general *Generic Drugs@fda.hhs.gov* email account are forwarded directly to DTP for consideration and tracking. Prioritization of guidance development is based on a variety of factors, including public health needs, industry demand for generic development, anticipated expiration of reference listed drug exclusivity, formulation features and predictability of in vivo performance, OGD experience with similar formulations or product types, and the feasibility of different approaches to demonstrate bioequivalence (*e.g.,* pharmacokinetic/pharmacodynamics studies, comparative clinical endpoint studies, and in vitro approaches). FDA anticipates that this targeted development approach will expedite the availability of product-specific guidances while supporting the important policies of transparency and maximizing benefit to the public health.

Second, FDA received comments regarding its proposed method of responding to requests related to issues for which the Agency has not yet determined a policy. Upon review of the comments, FDA is revising its recommendations related to such inquiries. As described in the guidance, if there is a better mechanism for a requestor to obtain comment from FDA on the subject of the request than through a controlled correspondence, the Agency will direct the requestor to such a mechanism, *e.g.,* a pre-abbreviated new drug application meeting request or the Regulatory Science Initiative. For requests for which the controlled correspondence pathway is the best mechanism, but that raise issues for which FDA has not determined appropriate policy, such requests will remain open until such policy decision is made.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on controlled correspondence related to generic drug development. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information has been approved under OMB control number 0910–0797.

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. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov*. (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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*.

Dated: September 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24621 Filed 9–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3327]

E6(R2) Good Clinical Practice; International Conference on Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''E6(R2) Good Clinical Practice.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance amends the guidance entitled ''E6 Good Clinical Practice: Consolidated Guidance'' (E6(R1)) to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting, and also updates standards regarding electronic records and essential documents. The draft guidance is intended to improve clinical trial quality and efficiency while maintaining human subject protection. FDA is making this draft guidance available for comment on the sections that are additions to ICH E6(R1) and marked as ''ADDENDUM.''

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 the sections of this draft guidance marked as