Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Guidance for Industry.'' The guidance document provides blood establishments that collect Whole Blood and blood components, including Source Plasma, with recommendations for further testing of donations that are reactive on a licensed donor screening test for anti-HCV, as required under § 610.40(e) (21 CFR 610.40(e)). The guidance also provides guidance to blood establishments on how to report the implementation of these recommendations.

In accordance with § 610.40(e), each donation, including autologous donations, found to be reactive by a donor screening test must be further tested using a licensed, approved or cleared supplemental test, when available. If no such supplemental test is available, blood establishments must perform one or more licensed, approved, or cleared tests as adequate and appropriate to provide additional information concerning the reactive donor's infection status (§ 610.40(e)). The guidance provides recommendations for adequate and appropriate testing under § 610.40(e), using a licensed HCV NAT (nucleic acid test) labeled with the supplemental indication and licensed anti-HCV donor screening tests or approved or cleared anti-HCV diagnostic tests that are currently available, to provide additional information concerning the donor's infection status. The guidance updates the recommendations related to the use of an appropriate multiantigen supplemental test contained in ''Guidance for Industry: 'Lookback' for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV'' dated December 2010 (available at: *https://www.fda.gov/media/124265/download*).

In the **Federal Register** of September 25, 2018, (83 FR 48446), FDA announced the availability of the draft guidance of the same title dated September 2018. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 2018.

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 further testing of donations that are reactive on a licensed donor screening test for antibodies to hepatitis C virus. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR part 610 and 21 CFR part 630 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or *https://www.regulations.gov.*

Dated: September 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21506 Filed 10–2–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1246]

Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment.'' The purpose of this guidance is to help sponsors design and conduct nonclinical studies needed to support initiation of clinical trials, ongoing clinical development, and marketing approval of enzyme replacement therapy (ERT) products. This guidance incorporates the comments received for and finalizes the draft guidance of the same title issued May 13, 2015.

DATES: The announcement of the guidance is published in the **Federal Register** on October 3, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–1246 for ''Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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.

FOR FURTHER INFORMATION CONTACT: Jenny Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5345, Silver Spring, MD 20903, 301–796–1023; or Sushanta Chakder, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5108, Silver Spring, MD 20903, 301–796–0861.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment.'' The nonclinical study requirements for ERT products may be different from products used to treat other diseases because of the rare, seriously debilitating, and life-threatening nature of the diseases treated by ERT products. Currently, there is no other final guidance that provides recommendations about the substance and scope of nonclinical information needed to support initiation of clinical trials, ongoing clinical development, and marketing approval of ERT products. This guidance provides consistent recommendations for nonclinical studies to expedite developments of ERT products used to treat these rare, life-threatening conditions, especially in pediatric patients.

This guidance finalizes the draft guidance of the same title issued May 13, 2015. All public comments received on the draft guidance have been considered, and the guidance has been revised as appropriate, along with a few editorial changes. Changes from the draft to the final include the following: ''Changes in disease-specific biomarkers'' has been added as a pharmacodynamic endpoint; a statement on the preference for animal disease models in assessing pharmacodynamic activity has been added; safety pharmacology parameters to proof-of-concept studies were added; a statement was added to clarify the exposure margins; a clarification on the rapidly progressing disease phenotype was provided by adding ''approximately'' 1 year; a statement on the 3-month toxicology study in one species to support marketing approval was added; and a statement on recovery animals was added.

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 ''Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved 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 collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, and the information collection in the regulations on good laboratory practice for nonclinical laboratory studies (21 CFR part 58) is approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: September 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21507 Filed 10–2–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1707]

Teva Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications for Pemoline Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 4, 2019. That notice, withdrawing approval of five abbreviated new drug applications for pemoline products, contained an incorrect website address for an archived web page of a *Postmarket Drug Safety Information for Healthcare Professionals* communication that FDA issued on October 24, 2005, stating its conclusion that the overall liver toxicity risk of CYLERT (new drug applications 016832 and 017703) and generic pemoline products outweighed the benefits of these products. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug