

• **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]

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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

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 2019 (84 FR 25811), appearing on page 25811 in FR Doc. 2019-11519, the following correction is made:

On page 25811, in the last paragraph of the third column, the website address, <https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/DrugsDrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126461.htm>, is corrected to read <https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126461.htm>.

Dated: September 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-21526 Filed 10-2-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Autism Spectrum Disorder (ASD) Research Portfolio Analysis, NIMH

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork

Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: The Office of Autism Research Coordination, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9663, Room 6184, Bethesda, Maryland, 20892 or can email your request, including your address to: iaccpublicinquiries@mail.nih.gov or nimhprapubliccomments@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Autism Spectrum Disorder (ASD) Research Portfolio Analysis, NIMH, 0925-0682, expiration date 12/31/2019, EXTENSION, National Institute of Mental Health (NIMH, National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of the ASD research portfolio analysis is to collect research funding data from U.S. and international ASD research funders, to assist the Interagency Autism Coordinating Committee (IACC) in fulfilling the requirements of the Combating Autism Act, and to inform the committee and interested stakeholders of the funding landscape and current directions for ASD research. Specifically, these analyses will continue to examine the extent to which current funding and research topics align with the *IACC Strategic Plan for ASD Research*. The findings will help guide future funding priorities by outlining current gaps and opportunities in ASD research as well as serving to highlight annual activities and research progress.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 520.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
U.S. Federal	22	63	15/60	347
U.S. Private	8	75	15/60	150
International Government	4	14	15/60	14
International Private	4	9	15/60	9
Total		2,078		520

Dated: September 23, 2019.

Melba O. Rojas,

Project Clearance Liaison, National Institute of Mental Health, National Institutes of Health.

[FR Doc. 2019-21523 Filed 10-2-19; 8:45 am]

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