DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0987]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document entitled ''Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications'' that appeared in the **Federal Register** of August 1, 2014. The document announced the generic clearance for the collection of qualitative data on tobacco products and communications. The document was published with the incorrect docket number. This document corrects that error.

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 FR Doc. 2014–18195, appearing on page 44779 in the **Federal Register** of August 1, 2014 (79 FR 44779), FDA is making the following correction:

1. On page 44779, in the second column, in the Docket No. heading, ''FDA–2014–N–0005'' is corrected to read ''FDA–2014–N–0987.''

Dated: December 3, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28714 Filed 12–8–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1275]

General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products.'' The draft guidance is intended to assist those sponsors of new drug applications (NDAs), biologics license applications (BLAs) for therapeutic biologics, and supplements to such applications who are planning to conduct clinical studies in pediatric populations. Effectiveness, safety, or dose finding studies in pediatric patients involve gathering clinical pharmacology information, such as information regarding a product's pharmacokinetics and pharmacodynamics pertaining to dose selection and individualization. This draft guidance addresses general clinical pharmacology considerations for conducting studies so that the dosing and safety information for drugs and biologic products can be sufficiently characterized, leading to well-designed trials to evaluate effectiveness.

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 February 9, 2015.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist those offices in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on 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: Gilbert J. Burckart, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3184, Silver Spring, MD 20993–0002, 301–796–2065.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products.'' During the past two decades, FDA has worked to address the problem of inadequate pediatric testing and inadequate pediatric use information in drug and biological product labeling. The Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) addressed the need for improved information about drug use in the pediatric population (codified at 21 U.S.C. 355a) by establishing incentives for conducting pediatric studies on drugs while exclusivity or patent protection exists. Congress subsequently passed the Best Pharmaceuticals for Children Act (BPCA) in 2002 and the Pediatric Research Equity Act (PREA) in 2003. Both BPCA and PREA were reauthorized in 2007 and were made permanent under Title V of the Food and Drug Administration Safety and Innovation Act of 2012 (Public Law 112–144).

Under BPCA, sponsors of certain applications and supplements filed under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (the FD&C Act) can obtain an additional 6 months of exclusivity if, in accordance with the requirements of the statute, the sponsor submits information responding to a written request from the Secretary relating to the use of a drug in the pediatric population.

Under PREA, sponsors of certain applications and supplements filed under section 505 of the FD&C Act or section 351 of the Public Health Service Act are required to submit pediatric assessments, unless they receive an applicable waiver or deferral of this requirement. If applicable, sponsors must submit a request for a deferral or waiver as part of an initial pediatric study plan.

This draft guidance focuses on the clinical pharmacology information (*e.g.,* exposure-response, pharmacokinetics, and pharmacodynamics) needed to