generated for submission to the regulatory authorities.

Since the E2C(R2) draft guidance was made available in 2012, ICH has identified questions linked to the interpretation and application of the E2C(R2) guidance. The E2C(R2) Q&A guidance is intended to clarify questions relating to implementation of the E2C(R2) guidance.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the current thinking of FDA on the E2C(R2) PBRER. They do not establish any rights for any person and are 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. The Paperwork Reduction Act of 1995

These guidances refer 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 (PRA) (44 U.S.C. 3501–3520). The collection of information in the ''Guidance on Reporting in Accordance with International Council for Harmonisation—Periodic Benefit-Risk Evaluation Report (E2C(R2)) and Providing Waiver-Related Materials'' has been approved under OMB control number 0910–0771. The guidances also reference other collections of information. The collection of information in 21 CFR 314.80 has been approved under OMB control number 0910–0230, and the collection of information in 21 CFR 600.80 has been approved under OMB control number 0910–0308.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: July 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17009 Filed 7–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0873]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

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 18, 2016.

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 OMB control number 0910–0537. 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, Three White Flint North 10A–12M, 11601 Landsdown Street, North Bethesda, MD 20852, *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.

Bar Code Label Requirement for Human Drug Products and Blood; OMB Control No. 0910–0537—Extension

In the **Federal Register** of February 26, 2004 (69 FR 9120), FDA issued a final rule that requires human drug product and biological product labels to have bar codes. Specifically, the rule requires bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. The rule also requires machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the NDC number for the product. For blood and blood components, the rule specifies the minimum contents of the label in a format that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research. We believe the rule helps to reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

While most of the information collection burdens created by the final rule have now been incorporated into currently approved information collections supporting the applicable regulations, respondents to the collection may continue to seek an exemption from the bar code label requirement under § 201.25(d) (21 CFR 201.25(d)). Section 201.25(d) requires submission of a written request for an exemption and describes the information that must be included in such a request. Based on the number of exemption requests we have received previously, we estimate that approximately 2 exemption requests will be submitted annually and that each exemption request will require 24 hours to complete. This results in an annual reporting burden of 48 hours, as reflected below in Table 1.

In the **Federal Register** of December 15, 2015 (80 FR 77637) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
201.25(d)	2	1	2	24	48

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: *July 13, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17044 Filed 7–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Pediatric Clinical Investigator Training Workshop; 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** on June 16, 2016 (81 FR 39271). The document announced a ''Pediatric Clinical Investigator Training'' workshop and contained an incorrect Web link for registration and an incorrect Web link for more information on the workshop. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *terrie.crescenzi@fda.hhs.gov* or Betsy Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *elizabeth.sanford@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Thursday, June 16, 2016, in FR Doc. 2016–14230, on page 39272, the following corrections are made:

1. On page 39272, in the first column, in the first paragraph under the ''Workshop Attendance and Participation'' heading, the first sentence is corrected to read ''If you wish to attend this workshop, visit *https://www.eventbrite.com/e/pediatric-clinical-investigator-training-workshop-tickets-19708166657.*

2. On page 39272, in the first column, in the second paragraph under the ''Workshop Attendance and Participation'' heading, the first sentence is corrected to read ''Registration information, the agenda, and additional background materials can be found at *http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm506658.htm.*

Dated: July 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17015 Filed 7–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request—Scholarships for Disadvantaged Students Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 19, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Scholarships for Disadvantaged Students (SDS) Program.

OMB No. 0915–0149—Revision.

Abstract: The program specific form for the SDS program has been revised to reflect a change in the order of the fields only. Fields K (Public or Non Profit Institution) and H (Point of Contact) have been moved to fields A and B respectively. Now Field A is Public or Non Profit Institution and Field B is Point of Contact. All other fields remained in sequence but were renamed with the appropriate letter order.

Need and Proposed Use of the Information: The purpose of the SDS Program is to provide funds to eligible schools to provide scholarships to full-time, financially needy students from disadvantaged backgrounds enrolled in health professions programs. To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the Public Health Service (PHS) Act). A school must meet the eligibility criteria to demonstrate that the program has achieved success based on the number and/or percentage of disadvantaged students who graduate from the school. In awarding SDS funds to eligible schools, funding points must be given to schools based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities (section 737(c) of the PHS Act).

Likely Respondents: The respondents are institutions that will be applying to the SDS program every four years.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time