''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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: Irene Z. Chan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4420, Silver Spring, MD 20993–0002, 301–796–3962.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Safety Considerations for Product Design to Minimize Medication Errors.'' The guidance is intended for sponsors of INDs; applicants of NDAs, BLAs, and ANDAs; and manufacturers of prescription drugs marketed without an approved application or OTC monograph drugs. This guidance provides sponsors, applicants, and manufacturers with a set of principles to consider while developing drug products using a systems approach to minimize medication errors relating to product design and container closure design. The recommendations in this guidance document are intended to provide best practices on how to improve the drug product and container closure design for all prescription and nonprescription drug products. The guidance also provides examples of product designs that resulted in postmarketing error.

This guidance document, which focuses on minimizing risks associated with the design of the drug product and its container closure system, is the first in a series of three planned guidances to minimize or eliminate hazards contributing to medication errors. The second guidance focuses on minimizing risks with the design of drug product container labels and carton labeling. The third guidance focuses on minimizing risks when developing and selecting proposed proprietary names for drugs.

In the **Federal Register** of December 13, 2012 (77 FR 74196), FDA announced the availability of the draft guidance entitled ''Safety Considerations for Product Design to Minimize Medication Errors.'' The Agency has carefully reviewed and considered the comments it received in developing this final version of the guidance. The Agency has made revisions to the guidance to address public comments requesting clarifications and implement formatting changes for improved readability as it deemed appropriate. The Agency also moved recommendations appropriate for labels and labeling to a separate guidance. The guidance announced in this notice finalizes the draft guidance dated December 2012.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on addressing safety achieved through drug product design to minimize medication errors. 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. 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.*

III. 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 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

IV. Electronic Access

You may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08335 Filed 4–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0768]

Donor Screening Recommendations To Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Monday, March 7, 2016 (81 FR 11808). The document announced a guidance for industry entitled ''Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products.'' The document was published with an incorrect docket number in the **ADDRESSES** section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In FR Doc. 2016–04893, appearing on page 11808 in the **Federal Register** of Monday, March 7, 2016, the following correction is made:

1. On page 11808, in the third column, the docket number is corrected to read ''FDA–2016–D–0768''.

Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08330 Filed 4–11–16; 8:45 am]

BILLING CODE 4164–01–P