DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry; Availability; 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 30, 2015 (80 FR 37273). The document announced the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The document was published with an incorrect table title and contents. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, 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. 2015–16013, appearing in the **Federal Register** of Tuesday, June 30, 2015, the following corrections are made:

1. On page 37274, in the first column, the title of table 2, ''Table 2. Revised Draft Product-Specific BE Recommendations for Drug Products Cholestyramine'' is corrected to read ''Table 2. Revised Draft Product-Specific BE Recommendations for Drug Products''.

2. On page 37274, in the first column, in the first line of the table under table 2, ''Cholestyramine'' is added to precede ''Doxycycline hyclate, Prasugrel hydrochloride, Tiagabine hydrochloride''.

Dated: July 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18024 Filed 7–22–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0449]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Sun Protection Factor Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug 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 24, 2015.

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 0910–0717. 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

SPF Labeling and Testing Requirements for OTC Sunscreen Products Containing Specified Active Ingredients and Marketed Without Approved Applications, and Drug Facts Labeling for All OTC Sunscreen Products—21 CFR 201.327(a)(1) and (i), 21 CFR 201.66(c) and (d) (OMB Control Number 0910–0717)—Extension

In the **Federal Register** of June 17, 2011 (76 FR 35620), we published a final rule establishing labeling and effectiveness testing requirements for certain OTC sunscreen products containing specified active ingredients without approved applications (2011 sunscreen final rule; § 201.327 (21 CFR 201.327)). In addition to establishing testing requirements, this sunscreen final rule lifts the delay of implementation of the prior 1999 sunscreen final rule (published May 21, 1999, at 64 FR 27666 and stayed December 31, 2001, 66 FR 67485) from complying with the 1999 labeling final rule (published March 17, 1999, 64 FR 13254) in which we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR part 201). Specifically, the 1999 labeling final rule added new § 201.66 to part 201. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products. We specifically exempted OTC sunscreen products from complying with the 1999 labeling final rule until we lifted the stay of the 1999 sunscreen final rule. The 2011 sunscreen final rule became effective December 17, 2012, for sunscreen products with annual sales of $25,000 or more and December 17, 2013, for sunscreen products with annual sales of less than $25,000 when we published an extension date notice on May 11, 2012 (77 FR 27591).

SPF Labeling and Testing for OTC Sunscreens Containing Specified Active Ingredients and Marketed Without Approved Applications

In the **Federal Register** of June 17, 2011 (76 FR 35678), we published a 60-day notice requesting public comment on the proposed collection of information in regard to SPF labeling and testing requirements for OTC sunscreen products containing specified ingredients and marketed without approved applications. In that notice, we stated that § 201.327 (a)(1) requires the principal display panel (PDP) labeling of a sunscreen covered by the 2011 final rule to include the SPF value determined by conducting the SPF test outlined in § 201.327(i). Therefore, this provision results in information collection with a third-party disclosure burden for manufacturers of OTC sunscreens covered by the rule. We determined that products need only complete the testing and labeling required by the rule one time, and then continue to utilize the resultant labeling (third-party disclosure) going forward without additional burden. This one-time testing would need to be conducted within the first 3 years after publication of the 2011 final rule for all