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]

BILLING CODE 4164–01–P

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

OTC sunscreens covered by that rule. We determined that the third-party disclosure burden by manufacturers of OTC sunscreens covered by the rule was based on an estimate: (1) Of the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information; (2) on the conduct of SPF testing based on the estimated number of existing formulations; (3) of the time to relabel currently marketed OTC sunscreens containing specified ingredients and marketed without approved applications; and (4) on testing and labeling of new products introduced each year. The estimate for this burden in the 2011 60-day PRA notice was a total of 30,066 hours in years one and two and a total burden of 966 in each subsequent year.

All currently marketed OTC sunscreen drug products are required at this time to be in compliance with the SPF labeling requirements specified by the 2011 final rule. However, our original estimate included the burden of new products introduced each year. We estimated that as many as 60 new OTC sunscreen products stock keeping units (SKUs) may be introduced each year which will have to be tested and labeled with the SPF value determined in the test. We estimated that the 60 new sunscreen SKUs represent 39 new formulations. The burden for testing and labeling these formulations was estimated at 30 hours per year.

We have received no further comments on our estimate of burden for the collection of this information other than two comments (FDA–2011–N–0449–0002 and FDA–2011–N–0449–0003). These comments were already addressed in FDA's notice of ''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'' published on May 9, 2012 (77 FR 27230).

In the **Federal Register** of April 16, 2015 (80 FR 20499), 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 THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	No. of respondents	No. of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Conduct SPF testing in accordance with § 201.327(i) for new sunscreens.	20	1.95	39	24	936
Create PDP labeling in accordance with § 201.327(a)(1) for new sunscreen SKUs.	20	3	60	0.5 (30 min.)	30
Total					966

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

Drug Facts Labeling for OTC Sunscreens

Because the 2011 final rule also lifts the delay of implementation of the Drug Facts regulations (§ 201.66) for OTC sunscreens, the rule also modifies the information collection associated with § 201.66 (currently approved under OMB control number 0910–0340) and adds an additional third-party disclosure burden resulting from requiring OTC sunscreen products to comply with Drug Facts regulations. In the **Federal Register** of March 17, 1999 (64 FR 13254), 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, codified in § 201.66 (the 1999 Drug Facts labeling final rule). Section 201.66 sets requirements for the Drug Facts portion of labels on OTC drug products, requiring such labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. Therefore, currently marketed OTC sunscreen products will incur a one-time burden to comply with the requirements in § 201.66(c) and (d). The burden was estimated in the 60-day PRA notice published in the **Federal Register** of June 17, 2011 (76 FR 35678), as 43,200 hours for existing sunscreen SKUs and 720 hours for new sunscreen SKUs.

The compliance dates for the 2011 final rule lifting the delay of the § 201.66 labeling implementation data for OTC sunscreen products were 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, respectively, when we published an extension date notice on May 11, 2012 (77 FR 27591). All currently marketed sunscreen products are, therefore, already required to be in compliance with the Drug Facts labeling requirements in § 201.66 and will incur no further burden in the 1999 labeling final rule. However, new OTC sunscreen drug products will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. In the 2011 60-day PRA, we estimated that as many as 60 new product SKUs marketed each year will have to comply with Drug Facts regulations. We estimated that these 60 SKUs would be marketed by 30 manufacturers. We estimated that approximately 12 hours would be spent on each label, based on the most recent estimate used for other OTC drug products to comply with the Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens. This is equal to 720 hours annually (60 SKUs × 12 hours/SKU). We stated that we do not expect any OTC sunscreens to apply for exemptions or deferrals of the Drug Facts regulations in § 201.66(e). However, we took this into consideration in 2013 and estimated the burden for an exemption or deferral by considering the number of exemptions or deferrals we have received since publication of the 1999 final rule (one response) and estimating that a request for deferral or exemption would require 24 hours to complete. Multiplying the annual frequency of response (0.125) by the number of hours per response (24) gives a total response time for requesting an exemption or deferral equal to 3 hours.

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	No. of respondents	No. of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Format labeling in accordance with § 201.66(c) and (d) for new sunscreen SKUs.	20	3	60	12	720
Request for Drug Facts exemption or deferral § 201.66(e).	1	0.125	0.125	24	3
Total					723

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

Dated:' July 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18026 Filed 7–22–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Julia Bitzegeio, Ph.D., Aaron Diamond AIDS Research Center: Based on the Respondent's admission, an assessment conducted by the Aaron Diamond AIDS Research Center (ADARC), and analysis conducted by ORI in its oversight review, ORI found that Dr. Julia Bitzegeio, former Postdoctoral Fellow, ADARC, engaged in research misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants R01 AI078788, R21 AI093255, and R37 AI064003.

ORI found that Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in one (1) publication, two (2) unfunded grant applications, and one (1) unpublished manuscript:

Journal of Virology 87:3549–3560, 2013 (hereafter referred to as ''*JVI* 2013'').

- R01 AI114367–01A1
- R01 AI120787–01
- ''A single amino acid in the CD4 binding site of HIV–1 Env is a key determinant of species tropism.'' Unpublished manuscript

Specifically, ORI found that:

1. Respondent falsified and/or fabricated in vitro rates of viral replication or infection in human and macaque lymphocytes and infectious titers on reporter cells, for multiple strains of SIV based chimeric viruses such that the results were not accurately represented in:

- Figure 7 in *JVI* 2013
- Figures 6B and 8C in R01 AI114367–01A1
- Figures 1, 2B, and 3B in R01 AI120787–01
- Figures 1A–D, 2D, 3D, 5A–C, 5I, 6C, and S3D in the unpublished manuscript

2. Respondent falsified and/or fabricated in vitro binding data of SIV based chimeric viruses to human or macaque CD4 such that the results were not accurately represented in:

- Figure 6 in R01 AI120787–01
- Figures 5D–F in the unpublished manuscript

ADARC has submitted a request for correction of *JVI* 2013.

Dr. Bitzegeio has entered into a Voluntary Settlement Agreement and has voluntarily agreed:

(1) That if within three (3) years from the effective date of the Agreement, Respondent receives or applies for U.S Public Health Service (PHS) support, Respondent agreed to have her research supervised for a period of three (3) years beginning on the date of her employment in a position in which she receives or applies for PHS support and to notify her employer(s)/institution(s) of the terms of this supervision; Respondent agreed that prior to the submission of an application for PHS support for a research project on which her participation is proposed and prior to her participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of her research contribution; Respondent agreed that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that if within three (3) years from the effective date of the Agreement, Respondent receives or applies for PHS support, Respondent agreed that any institution employing her shall submit in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on June 23, 2015.

FOR FURTHER INFORMATION CONTACT: Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Donald Wright,

Acting Director, Office of Research Integrity.

[FR Doc. 2015–18088 Filed 7–22–15; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning