$$\overline{T(\lambda)}$$

$$\overline{A(\lambda)}$$

$$\overline{A(\lambda)} = -\log \overline{T(\lambda)}$$

8. On page 6270, in the third column, the formula under § 201.327(j)(7) is corrected to read:

$$\int_{290}^{\lambda c} A(\lambda)d\lambda = 0.9 \int_{290}^{400} A(\lambda)d\lambda$$

9. On page 6270, in the third column, the formula under § 201.327(j)(8) is corrected to read:

$$UVAI/UV = \frac{\int_{340}^{400} A(\lambda)d\lambda\, B(\lambda) / \int_{340}^{400} d\lambda}{\int_{290}^{400} A(\lambda)d\lambda\, B(\lambda) / \int_{290}^{400} d\lambda}$$

Elsewhere in this issue of the **Federal Register**, FDA is extending the comment period on the proposed rule.

Dated: April 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–07712 Filed 4–17–19; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 310, 347, and 352

[Docket No. FDA–1978–N–0018 (formerly Docket No. FDA–1978–N–0038)]

RIN 0910–AF43

Sunscreen Drug Products for Over-the-Counter Human Use; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the proposed rule that appeared in the **Federal Register** of February 26, 2019. In the proposed rule, FDA requested comments on its proposals relating to the regulation of over-the-counter (OTC) sunscreen monograph products. These proposals described the conditions under which the Agency proposes that OTC sunscreen monograph products are generally recognized as safe and effective and not misbranded. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published February 26, 2019 (84 FR 6204). Submit either electronic or written comments by June 27, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 27, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 27, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–1978–N–0018 (formerly Docket No. FDA–1978–N–0038) for ''Sunscreen Drug Products for Over-the-Counter Human Use.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristen Hardin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5443, Silver Spring, MD 20993, 240–402–4246.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 26, 2019, FDA published a proposed rule with a 90-day comment period to request comments on the Agency's proposals relating to the regulation of OTC sunscreen monograph products. These proposals described the conditions under which the Agency proposes that OTC sunscreen monograph products are generally recognized as safe and effective and not misbranded. Comments on these proposals will inform FDA's rulemaking to establish regulations putting into effect a final monograph for nonprescription, OTC sunscreen drug products. FDA also indicated in the proposed rule that the Agency would consider requests to defer further rulemaking with respect to specific sunscreen active ingredients to allow the submission of new safety and/or effectiveness data to the record if such requests were submitted to the docket within the initial 90-day comment period. Elsewhere in this issue of the **Federal Register**, the Agency is publishing a correction to the proposed rule to clarify illegible graphics of equations.

The Agency has received a request for a 60- to 90-day extension of the comment period for the proposed rule. This request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the request and is extending the comment period for the proposed rule for 30 days, until June 27, 2019. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues. We note that this 30-day extension applies both to comments and to requests for the Agency to defer further rulemaking with respect to specific sunscreen active ingredients.

Dated: April 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–07710 Filed 4–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2019–0150]

RIN 1625–AA08

Special Local Regulation; Kailua Bay, Ironman World Championship, Kailua-Kona, Hawaii

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a recurring special local regulation for certain waters of Kailua Bay, Hawaii. This action is necessary to provide for the safety of life on these navigable waters located at Kailua-Kona, HI, during the swim portion of the Ironman World Championship Triathlon and practice swim held on consecutive Saturdays annually in October. This proposed rulemaking would prohibit persons and vessels from being in the regulated area each day of the event unless authorized by the Captain of the Port Honolulu. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 20, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2019–0150 using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Chief Jason Olney, Waterways Management Division, U.S. Coast Guard Sector Honolulu; telephone (808) 522–8265, email *jason.r.olney@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register