4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[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; Correction

AGENCY:  Food and Drug Administration, HHS.

ACTION:  Proposed rule; correction.

SUMMARY:  The Food and Drug Administration (FDA) is correcting a proposed rule relating to

the regulation of over-the-counter (OTC) sunscreen monograph products that appeared in the

*Federal Register* of February 26, 2019.  The document was published with formulas that were

illegible.  These corrections are being made to improve the accuracy of the proposed rule.

DATES:  Submit either electronic or written comments on the proposed rule by June 27, 2019.

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 (84 FR

6204), in FR Doc. 2019-03019, on pages 6267 through 6270, the following corrections are made:

1.  On page 6267, in the first column, the formula under § 201.327(i)(2)(ii)(B) is corrected to

    read:

$$E = \sum_{250}^{400} V_i\,(\lambda) * I(\lambda) * t$$

2. On page 6268, in the second column, the formula under § 201.327(i)(3)(ii)(C)(2) is corrected to read:

$$R = \frac{2 * (t_o - t_p)}{W_o + W_p}$$

3. On page 6268, in the second column, the formulas under § 201.327(i)(3)(ii)(D)(2)(*i*) are corrected to read:

$$\text{Percent Oxybenzone} = \frac{\text{Peak area of oxybenzone in sunscreen standard}}{\text{Peak area of oxybenzone in HPLC reference standard}} * 100$$

$$\text{Percent Padimate O} = \frac{\text{Peak area of padimate O in sunscreen standard}}{\text{Peak area of padimate O in HPLC reference standard}} * 100$$

4. On page 6269, in the third column, the formula under § 201.327(i)(7)(i) is corrected to read:

$$\text{SPFi} = \frac{\text{MEDp}}{\text{final MEDu}}$$

5. On page 6269, in the third column, the formulas under § 201.327(i)(7)(ii) are corrected to read:

$$\text{SPF} (\overline{\text{SPF}})$$

$$\overline{\text{SPF}} - (t * \text{SE})$$

6. On page 6270, in the second column, the formula under § 201.327(j)(4)(ii) is corrected to read:

$$\overline{T(\lambda)} = \frac{\sum_1^n P(\lambda)/n}{\sum_1^n C(\lambda)/n}$$

7. On page 6270, in the third column, the formulas under § 201.327(j)(5)(i) are corrected to read:

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

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

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

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: 4/17/2019 8:45 am; Publication Date:  4/18/2019]