4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. FDA-2018-N-1097]

Good Guidance Practices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending its good guidance practices regulation to inform the public on how to electronically submit a draft of a proposed guidance to the Agency. This technical amendment is nonsubstantive.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Megan Velez, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4254, Silver Spring, MD 20993-0002, 301-796-9301.

SUPPLEMENTARY INFORMATION: FDA is amending 21 CFR 10.115(f)(3), good guidance regulations, by adding language on how the public can electronically submit drafts of proposed guidance documents to participate in the development and issuance of guidance documents. The amendment provides an option for submitting the draft of a proposed guidance to the Agency electronically through https://www.regulations.gov at Docket No. FDA-2013-S-0610.

Publication of this document constitutes final action on the change under the Administrative Procedure Act (5 U.S.C. 553). This technical amendment is nonsubstantive.

FDA therefore, for good cause, has determined that notice and public comment are unnecessary under 5 U.S.C. 553(b)(3)(B). Further, this rule places no burden on affected parties for which such parties would need a reasonable time to prepare for the effective date of the rule. Accordingly, FDA, for good cause, has determined this technical amendment to be exempt under 5 U.S.C. 553(d)(3) and that the rule can become effective upon publication.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 10 is amended as follows:

PART 10--ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for part 10 continues to read as follows:

Authority: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. In §10.115, add two sentences to the end of paragraph (f)(3) to read as follows:

§ 10.115 Good guidance practices.

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(f) * * *

(3) * * * If you wish to submit the draft of a proposed guidance document electronically, submit it through https://www.regulations.gov at Docket No. FDA-2013-S-0610. It is only necessary to submit one copy.

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Dated: March 20, 2018.

Leslie Kux,
Associate Commissioner for Policy.

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