4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1150

[Docket No. FDA-2012-N-0920]

User Fees; 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 regulations to update a link regarding user fee disputes. This technical amendment is non-substantive.

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

FOR FURTHER INFORMATION CONTACT: Nate Mease and Tamika Hopkins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending § 1150.15 (21 CFR 1150.15) to update the web address for information regarding user fee disputes. FDA's user fee dispute regulations currently link to FDA's general webpage on tobacco products. FDA is revising § 1150.15 to specifically direct firms to FDA's webpage on tobacco product user fees by replacing "https://www.fda.gov/tobacco-products" with "https://www.fda.gov/tobacco-products/manufacturing/tobacco-user-fees" in two places.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). The APA generally exempts rules from the requirements of notice and comment rulemaking when an agency "for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice

and public procedure thereon are impracticable, unnecessary, or contrary to the public interest" (5 U.S.C. 553(b)(B)).

FDA has determined that notice and public comment are unnecessary because this amendment to the regulation provides only technical or non-substantive, ministerial changes to specify the location of information on FDA's webpage regarding tobacco product user fee program. Such technical, non-substantive changes are "routine determination[s], insignificant in nature and impact, and inconsequential to the industry and to the public." (*Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012)) (quotation marks and citation omitted). Accordingly, FDA for good cause finds that notice and public procedure thereon are unnecessary for changing the cited FDA webpage on tobacco user fees.

In addition, FDA finds good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date of less than 30 days after publication as "provided by the agency for good cause found and published with the rule" (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for this correction to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 1150

Tobacco products, User fees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1150 is amended as follows:

PART 1150--USER FEES

1. The authority citation for part 1150 continues to read as follows:

Authority: 21 U.S.C. 371, 387a, 387b, 387i, 387s, 21 CFR 1100.1.

2. Amend § 1150.15 by revising paragraphs (a)(4) and (d) to read as follows:

§ 1150.15 Disputes.

(a) * * * *

(4) Sent to the address found on our Web site (https://www.fda.gov/tobacco-products/manufacturing/tobacco-user-fees).

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(d) A request for further Agency review under § 10.75 of this chapter may be submitted. Such a request must be submitted in writing by the domestic manufacturer or importer and received by FDA within 30 days from the date on FDA's response. The request for further Agency review must be legible, in English, and submitted to the address found on our Web site (https://www.fda.gov/tobacco-products/manufacturing/tobacco-user-fees).

Dated: February 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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