

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1500)

Complainant

v.

Mufeed Mustafa
d/b/a High Life Smoke Shop,

Respondent.

Docket No. C-15-11

Decision No. CR3488

Date: December 1, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Mufeed Mustafa, d/b/a High Life Smoke Shop, at 11345 West Buckeye Road, 104 B, Avondale, Arizona 85323, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that High Life Smoke Shop unlawfully utilized a self-service display in a non-exempt facility, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent High Life Smoke Shop had previously admitted to two violations of C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$500 civil money penalty against Respondent High Life Smoke Shop.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on October 9, 2014, CTP served the complaint on Respondent High Life Smoke Shop by United Parcel Service. In the complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time in

which to file an answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

Respondent High Life Smoke Shop has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- CTP previously issued a warning letter to Respondent High Life Smoke Shop on June 28, 2012, citing violations¹ of 21 C.F.R. pt. 1140 on April 19, 2012, at Respondent's business establishment, 11345 West Buckeye Road, 104 B, Avondale, Arizona 85323;
- On February 8, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-379, FDA Docket Number FDA-2013-H-0136, against Respondent High Life Smoke Shop for two violations of 21 C.F.R. pt. 1140 within a 12-month period. CTP alleged those violations to have occurred on April 19, 2012, and November 20, 2012;
- The previous action concluded when Mufeed Mustafa, Respondent's authorized representative, settled the claims on Respondent's behalf. On February 16, 2013, Mr. Mustafa signed an Acknowledgment Form in which he "admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that that violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on March 21, 2013;
- During a subsequent two-part inspection of Respondent's business establishment, 11345 West Buckeye Road, 104 B, Avondale, Arizona, 85323, conducted on

¹ In the complaint, CTP describes the action or actions that took place at Respondent High Life Smoke Shop's business establishment on April 19, 2012, as both "a violation" and as "violations." Complaint ¶ 9. In a previous administrative complaint dated February 7, 2013, and attached to the present complaint, however, CTP described three discrete violations at Respondent High Life Smoke Shop's business establishment on April 19, 2012: a violation of 21 C.F.R. § 1140.14(a), a violation of 21 C.F.R. § 1140.14(b)(1), and a violation of 21 C.F.R. § 1140.16(c). Therefore, I will infer that CTP's description in the present complaint of "a violation" occurring on April 19, 2012, was a typographical error.

March 19 and 26, 2014, FDA-commissioned inspectors documented the presence of a self-service display of cigarette tobacco.

These facts establish Respondent High Life Smoke Shop's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell a tobacco product to any person younger than 18 years of age. Further, under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. The regulations also require a retailer to sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange. 21 C.F.R. § 1140.16(c).

A \$500 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent Mufeed Mustafa, d/b/a High Life Smoke Shop. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/
Catherine Ravinski
Administrative Law Judge