

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1478)

Complainant

v.

Alena LLC / Mike Iskhakov
d/b/a Camelback Smoke Shop,

Respondent.

Docket No. C-14-2009

Decision No. CR3573

Date: January 13, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Alena LLC / Mike Iskhakov, d/b/a Camelback Smoke Shop, at 650 East Camelback Road, Phoenix, Arizona 85012, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Camelback Smoke Shop impermissibly sold cigarettes to minors, and failed to verify, by means of photo identification containing a date of birth, that a tobacco purchaser was 18 years of age or older, 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 Camelback Smoke Shop was previously held liable for two violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$2,000 civil money penalty against Respondent Camelback Smoke Shop.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on November 12, 2014, CTP served the complaint on Respondent Camelback Smoke Shop. 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 Camelback 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 Camelback Smoke Shop on January 3, 2013, citing violations of 21 C.F.R. pt. 1140 on December 4, 2012, at Respondent's business establishment, 650 East Camelback Road, Phoenix, Arizona 85012;
- On September 9, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-1263, FDA Docket Number FDA-2013-H-1069, against Respondent for two violations of 21 C.F.R. pt. 1140 within a 12-month period. CTP alleged those violations to have occurred on December 4, 2012, and March 14, 2013;
- The previous action concluded when, on November 8, 2013, an Administrative Law Judge issued an Initial Decision and Default Judgment finding Respondent liable for the violations. That Initial Decision became final and binding on the parties on December 9, 2013. Complaint ¶ 13;
- At approximately 1:53 PM on March 21, 2014, at Respondent's business establishment, 650 East Camelback Road, Phoenix, Arizona 85012, FDA-commissioned inspectors documented Respondent's staff selling a package of Marlboro Gold Pack 100's cigarettes to a person younger than 18 years of age. The inspectors also documented that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the purchaser of a tobacco product was 18 years of age or older.

These facts establish Respondent Camelback 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 cigarettes to any person younger than 18 years

of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photo identification containing the bearer's date of birth, that no cigarette or smokeless tobacco purchaser is younger than 18 years of age.

Under 21 C.F.R. § 17.2, a \$2,000 civil money penalty is permissible for four violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$2,000 against Respondent Alena LLC / Mike Iskhakov, d/b/a Camelback 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