Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-1382)

Complainant,

v.

Bootheel Petroleum Co., Inc. d/b/a B J's Kwik Shop,

Respondent.

Docket No. C-14-1895

Decision No. CR3472

Date: November 20, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Bootheel Petroleum Co., Inc. d/b/a B J's Kwik Shop, at 623 North State Route 25, Dexter, Missouri 63841, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that B J's Kwik Shop impermissibly sold a tobacco product to a minor, and failed to verify, by means of photo identification containing a date of birth, that the 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. An Administrative Law Judge (ALJ) has previously found Respondent to have committed two violations of regulations found at 21 C.F.R. pt. 1140. *See Bootheel Petroleum Co., Inc. d/b/a B J's Kwik Shop*, DAB CR3037, at 2-3 (2014); Complaint ¶ 11. Therefore, CTP seeks to impose a \$2,000 civil money penalty against Respondent BJ's Kwik Stop.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 24, 2014, CTP served the complaint on Respondent B J's Kwik 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 B J's Kwik 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 BJ's Kwik Shop on March 28, 2013, citing a violation of 21 C.F.R. pt. 1140 on March 12, 2013, at Respondent's business establishment, 623 North State Route 25, Dexter, Missouri 63841.
- On October 24, 2013, CTP initiated a civil money penalty action against Respondent, CRD Docket Number C-14-41, FDA Docket Number FDA-2013-H-1252. CTP cited two violations of 21 C.F.R. pt. 1140(a) within a twelve month period.
- On December 19, 2013, the previous civil money penalty action concluded when the ALJ issued an Initial Decision and Default Judgment against the Respondent in which he found Respondent committed two violations of 21 C.F.R. pt. 1140 by selling cigarettes to a minor on two separate occasions. The Initial Decision and Default Judgment became final and binding on January 18, 2014. *See Bootheel Petroleum Co., Inc. d/b/a B J's Kwik Shop*, DAB CR3037, at 2-3 (2014); Complaint ¶ 11.
- At approximately 11:49 a.m. on March 4, 2014, at Respondent's business establishment, 623 North State Route 25, Dexter, Missouri 63841, FDA-commissioned inspectors documented that a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco. The inspectors also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

These facts establish Respondent B J's Kwik 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 § 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 § 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 photographic identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.

A \$2,000 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$2,000 against Respondent Bootheel Petroleum Co., Inc. d/b/a B J's Kwik 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.

Catherine Ravinski

Administrative Law Judge