

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2015-H-0017)

Complainant,

v.

Khushi Enterprise LLC / Bintu Patel  
d/b/a On The Way,

Respondent.

Docket No. C-15-817

Decision No. CR3692

Date: March 6, 2015

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Khushi Enterprise LLC / Bintu Patel d/b/a On The Way, at 701 West Church Street, Cherryville, North Carolina 28021, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that On The Way unlawfully sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that tobacco purchasers were 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. CTP seeks to impose a \$500 civil money penalty against Respondent On The Way.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 7, 2014, CTP served the complaint on Respondent On The Way 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 On The Way 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:

- At Respondent's business establishment, 701 West Church Street, Cherryville, North Carolina 28021, on September 30, 2013, at approximately 6:39 PM, an FDA-commissioned inspector observed Respondent's staff sell a package of Winston Red Box cigarettes to a person younger than 18 years of age. The inspector also observed that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the tobacco purchaser was 18 years of age or older;
- In a warning letter issued on December 5, 2013, CTP informed Respondent of the inspector's observations from September 30, 2013, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). The letter further warned that if Respondent failed to correct its violations, the FDA could impose a civil money penalty or take other regulatory action;
- At Respondent's business establishment, 701 West Church Street, Cherryville, North Carolina 28021, on August 1, 2014, at approximately 6:50 PM, FDA-commissioned inspectors observed Respondent's staff sell a package of Newport Non-Menthol Box cigarettes to a person younger than 18 years of age. The inspectors also observed that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the tobacco purchaser was 18 years of age or older.

These facts establish Respondent'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 or smokeless tobacco 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.

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 Khushi Enterprise LLC / Bintu Patel d/b/a On The Way. 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