Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-1964)

Complainant,

v.

J B Express Greensboro LLC / Yong A Bryant d/b/a J B Express,

Respondent.

Docket No. C-15-435

Decision No. CR3599

Date: January 27, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, J B Express Greensboro LLC / Yong A Bryant d/b/a J B Express, at 2400 Randleman Road, Greensboro, North Carolina 27406, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that J B Express unlawfully sold individual cigarettes and sold cigarettes to minors, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. CTP seeks to impose a \$250 civil money penalty against Respondent J B Express.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on November 25, 2014, CTP served the complaint on Respondent J B Express 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 J B Express 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 an unspecified time on October 11, 2013, at Respondent's business establishment, 2400 Randleman Road, Greensboro, North Carolina 27406, an FDA-commissioned inspector observed the clerk on duty sell two individual Newport cigarettes to a customer;
- In a warning letter dated December 12, 2013, CTP informed Respondent of the inspector's October 11, 2013 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(d). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 10:15 a.m. on July 3, 2014, at Respondent's business establishment, 2400 Randleman Road, Greensboro, North Carolina 27406, FDA-commissioned inspectors observed that a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes.

These facts establish Respondent J B Express'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). The regulations prohibit the sale of individual cigarettes. 21 C.F.R. § 1140.14(d). The regulations also prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$250 against Respondent J B Express Greensboro LLC / Yong A Bryant d/b/a J B Express. 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