

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1719)

Complainant

v.

K.O.K. Limited Company /
Karry Out Korner 1, Inc.
d/b/a Karry Out Korner,

Respondent.

Docket No. C-15-198

Decision No. CR3536

Date: December 29, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, K.O.K. Limited Company / Karry Out Korner 1, Inc. d/b/a Karry Out Korner, at 302 South Washington Street, Ardmore, Oklahoma 73401 , and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Karry Out Korner impermissibly sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the 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 Karry Out Korner.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on October 30, 2014, CTP served the complaint on Respondent Karry Out Korner 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 Karry Out Korner 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 approximately 4:26 p.m. on November 7, 2013, at Respondent's business establishment, 302 South Washington Street, Ardmore, Oklahoma 73401, an FDA-commissioned inspector observed Respondent's staff selling a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco to a person younger than 18 years of age. The inspector also observed 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;
- In a warning letter dated January 16, 2014, CTP informed Respondent of the inspector's November 7, 2013 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). 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 8:22 p.m. on April 24, 2014, at Respondent's business establishment, 302 South Washington Street, Ardmore, Oklahoma 73401, FDA-commissioned inspectors documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age. 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 Karry Out Korner'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 tobacco products to any person younger than 18 years of age.

