Department of Health and Human Services DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2015-H-2921)

Complainant

v.

East End Kitchen and Market, LLC,

Respondent.

Docket No. C-15-3738

Decision No. CR4765

Date: December 29, 2016

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, East End Kitchen and Market, LLC, at 1159 Stratford Avenue, Bridgeport, Connecticut 06607, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that East End Kitchen and Market, LLC impermissibly sold cigarettes 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. The complaint likewise alleges that an Initial Decision and Default Judgment was previously entered against Respondent East End Kitchen and Market, LLC on March 6, 2015. The prior Default Judgment found Respondent liable for three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,000 civil money penalty against Respondent East End Kitchen and Market, LLC.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on August 27, 2015, CTP served the complaint on Respondent East End Kitchen and Market, LLC 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.

I. <u>Procedural History</u>

On September 14, 2015, Respondent timely requested an extension of time to file an answer. I granted Respondent's request on September 18, 2015, and extended Respondent's answer deadline to October 28, 2015. Subsequently, Respondent timely filed an answer.

On November 9, 2016, I scheduled this matter for a prehearing conference. The prehearing conference was scheduled for December 7, 2016 at 1:00 PM (Eastern). Both parties were notified of the time and date. The prehearing conference was held as scheduled on December 7, 2016. Representatives for CTP appeared on the call, however, Respondent failed to appear.

On December 7, 2016, I issued an Order requiring Respondent to show cause for its failure to appear at the prehearing conference. Respondent was warned that failure to respond to the December 7, 2016 Order could result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations in the complaint and imposing a civil money penalty. Respondent was given until December 21, 2016 to show cause. To date, Respondent has not responded to the December 7, 2016 Order. Therefore, pursuant to 21 C.F.R. § 17.35, I am striking Respondent's answer for failing to appear at the prehearing conference and failing to respond to my Order to show cause.

II. Default Decision

Striking Respondent's answer leaves the complaint unanswered. 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:

On January 13, 2015, CTP initiated a previous civil money penalty action, CRD Docket Number C-15-904, FDA Docket Number FDA-2015-H-0103, against Respondent¹ for three² violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred at Respondent's

¹ In the previous action, Respondent was identified as East End Kitchen and Market, LLC / Tageldin Banaga d/b/a East End Kitchen and Market.

² Two violations were documented on September 24, 2013, and two on July 28, 2014. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

- business establishment, 1159 Stratford Avenue, Bridgeport, Connecticut 06607, on September 24, 2013, and July 28, 2014;
- The previous action concluded when an Initial Decision and Default Judgment was entered on March 6, 2015, finding Respondent liable under the Act for the violations as alleged;
- At approximately 10:57 a.m. on May 13, 2015, at Respondent's business establishment, 1159 Stratford Avenue, Bridgeport, Connecticut 06607, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box 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 East End Kitchen and Market, LLC'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); 81 Fed Reg. 28,974, 28975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1)³, no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), 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.

Under 21 C.F.R. § 17.2, a \$5,000 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$5,000 against Respondent East End Kitchen and Market, LLC. 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/ Margaret G. Brakebusch Administrative Law Judge

³ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: https://federalregister.gov/a/2016-10685.