

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-1456)

Complainant

v.

Leah Minimarket, Inc.
d/b/a Leah's Mini Market,

Respondent.

Docket No. C-15-2276

Decision No. CR4179

Date: August 28, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Leah Minimarket d/b/a Leah's Mini Market, at 15 Healey Street, Springfield, Massachusetts 01151, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Leah's Mini Market impermissibly sold cigarettes to minors, failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and sold individual cigarettes, 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 \$2,000 civil money penalty against Respondent Leah's Mini Market.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on May 7, 2015, CTP served the complaint on Respondent Leah's Mini Market 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. Procedural History

On May 14, 2015, Respondent timely filed an answer to the complaint. On May 19, 2015, I issued an Acknowledgment and Pre-Hearing Order establishing a deadline of June 19, 2015 for both parties to serve requests for production of documents. CTP served Respondent with a Request for Production of Documents on June 18, 2015. Respondent failed to comply with the request.

On July 24, 2015, CTP filed a Motion to Compel Discovery and a Motion to Extend Deadlines. On July 27, 2015, I granted CTP's motions and ordered Respondent to comply with CTP's request for production of documents by August 24, 2015. Respondent was warned that failure to comply with the order may result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations in the complaint.

On July 30, 2015, Respondent filed a notice indicated it is in discussion with CTP to settle this matter. On August 3, 2015, Respondent completed an acknowledgment form, in which, it admitted to the violations in the complaint and agreed to make sufficient payment to settle the matter. Respondent was required to make payment to CTP by August 7, 2015. As of today, Respondent has not made any payment to CTP.

On August 25, 2015, CTP filed a Motion to Impose Sanctions indicating that Respondent has not produced any documents as requested and has failed to comply with my July 27, 2015 order. CTP has requested I strike the Respondent's answer and issue a default judgment against Respondent. Due to Respondent's noncompliance, I am granting CTP's motion for sanctions and striking Respondent's answer. 21 C.F.R. § 17.35 (c)(3).

II. Default Decision

Striking Respondent's answer leaves the complaint unanswered. Therefore, I am required to issue an initial decision by default if the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the complaint establish violations of the Act. 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 11:25 a.m. on June 25, 2014, at Respondent's business establishment, 15 Healey Street, Springfield, Massachusetts 01151, an FDA-commissioned inspector observed Respondent's staff selling a package of

Maverick Box 100s cigarettes 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 July 31, 2014, CTP informed Respondent of the inspector's June 25, 2014 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 3:31 p.m. on October 13, 2014, at Respondent's business establishment, 15 Healey Street, Springfield, Massachusetts 01151, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box 100s 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. Additionally, the inspectors observed that the minor received two individual cigarettes instead of change during the sales transaction.

These facts establish Respondent Leah's Mini Market'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 a tobacco product to any person younger than 18 years of age. Further, under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. Pursuant to under 21 C.F.R. § 1140.14(d), no retailer may sell or distribute individual cigarettes.

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 Leah Minimarket d/b/a Leah's Mini Market. 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