

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

West Seattle Tobacco Company LLC
d/b/a West Seattle Smoke Company,

Respondent.

Docket No. C-13-1141
FDA Docket No. FDA-2013-H-0935

Decision No. CR2981

Date: November 18, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, West Seattle Tobacco Company LLC d/b/a West Seattle Smoke Company, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. Respondent did not answer the Complaint, nor did Respondent request an extension of time within which to file an answer. Therefore, I enter a default judgment against Respondent and assess a civil money penalty of \$250.

CTP began this case by serving the Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent utilized a self-service display to offer regulated tobacco products for sale, 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. Part 1140 (2012). CTP seeks a civil money penalty of \$250.

On September 5, 2013, CTP served the Complaint on Respondent by United Parcel Service (UPS), pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that within 30 days Respondent should pay the proposed penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days, an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns West Seattle Smoke Company, an establishment that sells tobacco products and is located at 4748 California Avenue Southwest, Seattle, Washington 98116. Complaint ¶ 2.
- On October 24, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspector observed a violation of 21 C.F.R. § 1140.16(c) due to Respondent’s establishment utilizing “a self-service display in a non-exempt facility. Complaint ¶ 9.
- On December 13, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from October 24, 2012. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.16(c), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 9.

- The FDA did not receive a response to the Warning Letter. UPS records reflect that on December 17, 2012, the letter was delivered and accepted by “Amir.” Complaint ¶ 10.
- During a subsequent inspection conducted on April 9, 2013, and May 1, 2013, FDA-commissioned inspectors documented additional violations of 21 C.F.R. § 1140.16(c) at Respondent’s establishment. “Specifically, the establishment, which allows minors to enter when accompanied by an adult, has a customer-accessible display containing ‘General’ smokeless tobacco on the main sales floor.” Complaint ¶ 1.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, the regulations require retailers to sell cigarettes exclusively in face-to-face exchanges, without the use of devices such as self-service displays, 21 C.F.R. § 1140.16(c), except where the establishment does not permit any person younger than 18 years of age to be present or enter at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

Taking the above alleged facts as true, Respondent had two violations of regulations contained in 21 C.F.R. Part 1140 within a seven-month period. Specifically, Respondent had a violation on October 24, 2012, and a second violation during a two-part inspection conducted on April 9, 2013, and May 1, 2013. On October 24, 2012, Respondent violated the requirement that retailers sell cigarettes or smokeless tobacco exclusively in face-to-face exchanges, without the use of devices such as self-service displays, 21 C.F.R. § 1140.14(c); 21 C.F.R. § 1140.16(c), because Respondent’s establishment had a self-service display of regulated tobacco products and permitted persons younger than 18 years of age to enter with an adult, 21 C.F.R. § 1140.16(c)(2)(ii). Respondent’s actions on April 9, 2013, and May 1, 2013, were in violation of 21 C.F.R. § 1140.16(c), because the establishment utilized a display containing regulated tobacco products that provided consumers direct access to smokeless tobacco without restricting the facility to adults at all times. Therefore, Respondent has committed violations of law for which a civil money penalty is merited.

