

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Poojan, Inc. / Sanjay Patel
d/b/a Pee Dee Grocery,

Respondent.

Docket No. C-15-513
FDA Docket No. FDA-2014-H-2030

Decision No. CR3592

Date: January 20, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Poojan, Inc. / Sanjay Patel d/b/a Pee Dee Grocery that alleges facts and legal authority sufficient to justify the imposition of a \$250 civil money penalty. 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 \$250 civil money penalty.

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 used a self-service display in a non-exempt location and sold cigarettes to a minor, 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 (2013). CTP seeks a \$250 civil money penalty.

On December 4, 2014, CTP served the Complaint on Respondent by United Parcel Service, 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 [C]omplaint 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 Pee Dee Grocery, an establishment that sells tobacco products and is located at 9150 Highway 701 South, Conway, South Carolina 29527. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on January 16, 2014, an FDA-commissioned inspector “observed a self-service display of Longhorn brand smokeless tobacco located on the counter in an area of the establishment that is open to the general public during business hours.” Complaint ¶ 10.
- On March 13, 2014, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from January 16, 2014. The letter explained that the observation constituted a violation of regulations 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 ¶ 10.
- Although UPS records indicate that an individual named “Patel” received the Warning Letter, CTP never received a response to the Warning Letter. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on June 5, 2014, at approximately 11:31 AM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes” 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 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 tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). Moreover, a self-service display is a method of sale expressly prohibited by the regulations unless the self-service display is located in a facility in which the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. 21 C.F.R. § 1140.16(c)(2)(ii).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on June 5, 2014. Earlier, on January 16, 2014, Respondent violated 21 C.F.R. § 1140.16(c) by using a self-service display to sell tobacco products in a facility that was open to minors. Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. I thus find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/

Steven T. Kessel
Administrative Law Judge