

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

Stogie's, Inc.

d/b/a Stogie's Discount Tobacco and Beer,

Respondent.

Docket No. C-14-733

FDA Docket No. FDA-2014-H-0236

Decision No. CR3503

Date: December 5, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

I issue this default judgment against Respondent, Stogie's, Inc. d/b/a Stogie's Discount Tobacco and Beer, as a sanction for its failure to comply with the Center for Tobacco Products' (CTP's) discovery request. On November 13, 2014, I issued an order directing Respondent to comply with the request. Respondent failed to produce any documents by the deadline that I had set for compliance. I warned Respondent in my order that failure to comply with CTP's discovery request would be a basis for me to impose a default judgment against it.

CTP began this case by serving a 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's staff unlawfully utilized a self-service display of tobacco products in a non-exempt facility, sold tobacco products to a minor, and failed to verify, by means of photo identification containing a date of birth,

that a tobacco purchaser was 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$2,000.

On March 10, 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 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 issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

I issued an Initial Decision and Default Judgment in this case on May 2, 2014. Respondent timely answered the Complaint, however, the Civil Remedies Division (CRD) received Respondent's answer well after the filing deadline. On May 30, 2014, I vacated the decision and issued an Acknowledgment and Prehearing Order that set deadlines for the parties' submissions, including the September 7, 2014 deadline to request that the opposing party provide copies of documents relevant to this case.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Stogie's Discount Tobacco and Beer, an establishment that sells tobacco products and is located at 3477 US Route 60, Huntington, West Virginia 25705. Complaint ¶ 3.
- During an inspection of Respondent's establishment on February 6, 2013, at an undisclosed time, an FDA-commissioned inspector observed the presence of "a self-service display . . . of cigarette tobacco and smokeless tobacco . . . ." Specifically, "an employee on duty told the inspector that minors were allowed to enter with an adult." Complaint ¶ 10.
- On March 18, 2013, Shawn Stewart responded in writing to the Warning Letter on Respondent's behalf. "Mr. Stewart stated that the store posted a sign outside that stated that minors are not allowed inside and that the establishment's employees have been made aware of FDA policy." Complaint ¶ 11.
- During a subsequent two-part inspection on June 6, 2013 and June 11, 2013, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 at Respondent's establishment. Specifically, "a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack 72's cigarettes on June 6, 2013, at approximately 5:15 PM[.]" The inspectors also documented that "the minor's identification was not verified before the sale . . . on June 6, 2013, at

approximately 5:15 PM[.]” Additionally, “the establishment ha[d] a self-service display of smokeless tobacco in a customer-accessible aisle of the establishment [,][and] . . . minors [we]re able to enter the establishment at any time.” 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 sold or distributed 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 regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require the verification, by means of photo identification containing a purchaser’s date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Pursuant to 21 C.F.R. § 1140.16(c)(1), a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Self-service displays are a method of sale that is not permitted under the regulations, 21 C.F.R. § 1140.16(c)(1), except when located in facilities where 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 committed four violations of the regulations contained in 21 C.F.R. Part 1140 within a 24-month period. Specifically, on February 6, 2013, Respondent utilized a self-service display of regulated tobacco products, in violation of 21 C.F.R. § 1140.16(c). During a two-part inspection on June 6, 2013 and June 11, 2013, Respondent unlawfully sold a regulated tobacco product to a minor, failed to verify the purchaser’s age by means of photographic identification containing the purchaser’s date of birth, and utilized a self-service display of regulated tobacco products in violation of 21 C.F.R. § 1140.16(c). 21 C.F.R. § 1140.14(a) and (b)(1); 21 C.F.R. § 1140.16(c). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$2,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$2,000 is warranted and so order one imposed.

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/s/  
Steven T. Kessel  
Administrative Law Judge