

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Jay Ambaji Inc.  
d/b/a Smokers Palace,

Respondent.

Docket No. T-17-5308  
FDA No. FDA-2017-H-4241

Decision No. TB2393

Date: January 23, 2018

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) initiated an \$11,182 civil money penalty (CMP) action against Respondent for unlawfully selling tobacco products to minors, failing to verify that tobacco product purchasers were of sufficient age, and using a self-service display in a non-exempt facility, in violation of 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. In addition, Respondent Smokers Palace has previously admitted to four (4) violations of regulations found at 21 C.F.R. pt. 1140. During the hearing process, Respondent failed to follow several judicial directions and has failed to defend its case. I therefore strike Respondent's answer and issue this decision of default judgment.

## **I. Procedural History**

Respondent timely answered CTP's complaint. Judge Bill Thomas<sup>1</sup> issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for parties' submissions, including a November 17, 2017 deadline for CTP to file its prehearing exchange and a December 8, 2017 deadline for Respondent to file its prehearing exchange. On September 25, 2017, CTP, with Respondent's authorization, filed a Joint Status Report stating that "[t]he parties have been unable to reach a settlement in this case and intend to proceed to a hearing."

CTP filed its prehearing exchange on November 17, 2017. CTP's pre-hearing exchange included an Informal Brief of Complainant, a list of proposed witnesses and exhibits, and nineteen (19) numbered exhibits. CTP's exhibits included the declarations of three witnesses.

Respondent failed to file a prehearing exchange by the December 8, 2017 deadline set forth in Judge Thomas' APHO. Accordingly, on December 12, 2017, Judge Thomas issued an Order to Show Cause (OSC). In his OSC, Judge Thomas noted that Respondent's failure to file a prehearing exchange might indicate that it had abandoned its hearing request and ordered Respondent to file a written response by December 29, 2017, stating whether it wished to continue defending the action. Judge Thomas warned that failure to file a response could "result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty pursuant to 21 C.F.R. § 17.35(a)(2)."

Respondent failed to file a response to the OSC.

## **II. Striking Respondent's Answer**

Respondent failed to file a prehearing exchange by the date set forth in the APHO and failed to respond to the OSC to indicate whether it was still interested in defending this matter. In fact, Respondent has not made any direct contact with this Court since August 16, 2017, the date Respondent timely filed its answer. Respondent's failure to effectively prosecute and defend actions taken over the course of the proceedings have interfered with the orderly and speedy processing of this case, further warranting imposition of sanctions. *See* 21 C.F.R. § 17.35(a).

Due to Respondent's noncompliance with the August 25, 2017 APHO and its nonresponse to the December 12, 2017 OSC, I am striking Respondent's Answer, issuing

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<sup>1</sup> Judge Thomas was the administrative law judge assigned to this case before it was transferred to me on December 14, 2017.

this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. § 17.35(a), 17.11(a). The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and I find the failure to comply here sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b). Respondent failed to comply with the August 25, 2017 APHO and the December 12, 2017 OSC and it did not provide any adequate justification for its noncompliance.

### **III. 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.

For purposes of this decision, I assume the facts alleged in the Complaint are true and conclude that default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with my order. 21 C.F.R. § 17.11. Specifically:

- Respondent owns Smokers Palace, an establishment that sells tobacco products and is located at 1509 North Leroy Street, Fenton, Michigan 48430. Complaint ¶¶ 7-8.
- CTP initiated the first civil money penalty action, CRD Docket Number T-17-1707, FDA Docket Number FDA-2017-H-0261, against Respondent for four violations of 21 C.F.R. pt. 1140 within a 24-month period. Complaint ¶ 11
- The previous action concluded when Respondent "admitted all of the allegations in the Complaint and paid the agreed upon penalty." Further, "Respondent expressly waived its right to contest such violations in subsequent actions." Complaint ¶ 12.
- During a subsequent inspection of Respondent's establishment, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes" on May 24, 2017 at approximately 5:49 p.m. In addition, on May 31, 2017, an FDA-commissioned inspector observed a customer-accessible display containing Rave cigarette tobacco located on the main sales floor of the establishment. The inspector also observed a person younger than 18 years of age was able to enter the establishment and purchase a tobacco product on May 24, 2017. Complaint ¶ 9.

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)(1). The regulations also require retailers to verify, 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(a)(2), and, pursuant to the regulations, no retailer may utilize a self-service display in a non-exempt facility. 21 C.F.R. § 1140.16(c).

Taking the above alleged facts as true, Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on February 28, 2016, July 5, 2016, and May 24, 2017. On July 5, 2016, Respondent also violated the requirement that retailers verify, 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(a)(2). Finally, on July 6, 2016, and May 31, 2017, Respondent violated the prohibition against the use of self-service displays in a non-exempt facility. 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 \$11,182, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$11,182 is warranted and so order one imposed.

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/s/  
Steven T. Kessel  
Administrative Law Judge