

**Department of Health and Human Services  
DEPARTMENTAL APPEALS BOARD  
Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2016-H-4573)

Complainant

v.

V-12 Variety Store LLC  
d/b/a Steal Deal Apparel and Gift Shop,

Respondent.

Docket No. T-17-1404

Decision No. TB1674

Date: July 27, 2017

**ORDER GRANTING COMPLAINANT'S MOTION FOR SANCTIONS AND  
ISSUING INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, V-12 Variety Store LLC d/b/a Steal Deal Apparel and Gift Shop, located at 205 Bridge Street, Phoenixville, Pennsylvania 19460, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Respondent impermissibly sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, 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. Throughout this administrative process, Respondent has failed to comply with multiple judicial directions regarding CTP's discovery request. Therefore, I grant Complainant's Motion to Impose Sanctions, strike Respondent's answer, and issue this decision of default judgment against Respondent.

## **I. Procedural History**

On January 13, 2017, CTP properly served an administrative complaint seeking a \$275 civil money penalty on Respondent, Steal Deal Apparel and Gift Shop. On February 5, 2017, Respondent timely filed an answer to CTP's complaint. On February 8, 2017, I issued an Acknowledgment and Prehearing Order (APHO) that set deadlines for parties' actions, including the March 13, 2017, deadline to request relevant documents from the opposing party. CTP served Respondent with its request for documents on March 13, 2017.

On April 18, 2017, CTP filed a Motion to Compel Discovery indicating that Respondent did not respond to its request within the time allotted by the APHO. *See* 21 C.F.R. § 17.23(a). In a letter issued by my direction, I gave Respondent additional time, until May 4, 2017, to respond to CTP's motion. Respondent did not file a response.

On May 17, 2017, I issued an Order granting CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines to allow Respondent another opportunity to produce the requested documents. That Order allowed Respondent until June 1, 2017, to comply with CTP's discovery request. I explicitly warned Respondent that failure to comply with CTP's discovery request 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. Respondent did not comply with the CTP's discovery request within the time provided by the May 17, 2017 Order.

On June 5, 2017, CTP filed a Status Report and Motion to Impose Sanctions. In its Motion to Impose Sanctions, CTP stated that "Respondent has been provided with ample opportunity—approximately fifty additional days—to respond to CTP's RFP, but has not done so." Accordingly, CTP asked that I "issue an Initial Decision finding Respondent liable for selling tobacco products to a minor and failing to verify the age of a person purchasing tobacco products by means of photographic identification on June 15, 2016, as alleged in the Complaint . . . and imposing a \$275 civil money penalty against Respondent." In a June 8, 2017 letter issued by my direction, I allowed Respondent until June 22, 2017, to respond to CTP's motion. Respondent has to date failed to file a response to CTP's motion.

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

In my APHO, I warned the parties that I could issue sanctions pursuant to 21 C.F.R. § 17.35, including but not limited to, dismissal of the complaint or answer, if, among other reasons, a party failed to comply with any order I issued in this matter, or failed to prosecute or defend its case. As outlined above, Respondent has failed to participate in the defense of its case and repeatedly failed to comply with my Orders. Sanction is therefore appropriate pursuant to 21 C.F.R. § 17.35(a). The issue is whether CTP's proposed sanction – striking Respondent's Answer and issuing default judgment – is the

appropriate one. The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply. *See* 21 C.F.R. § 17.35(b).

Here, I find Respondent's failure to participate in the defense of its case and its refusal to comply with orders sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. First, Respondent has failed to produce any documents, object to any of requests, or file responses to motions. This refusal to participate has caused unnecessary delay in the adjudicative process. Second, Respondent has failed to comply with orders issued to address its failure to participate in its defense. Specifically, Respondent failed to comply with my initial APHO requiring responses to discovery requests; failed to respond to CTP's Motion to Compel in the time I provided in a subsequent order; failed to produce documents in compliance with my order granting CTP's Motion to Compel, and failed to submit pre-hearing submissions as provided in that same order. Respondent's persistent non-compliance with my orders and refusal to participate in the defense of its case warrants severe sanction. *See* 21 C.F.R. §§ 17.35(a)(1), 17.35(c) (3); 17.35(d).

Accordingly, I am striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. 21 C.F.R. §§ 17.11(a).

### **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 the default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with the orders. 21 C.F.R. § 17.11. Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Steal Deal Apparel and Gift Shop, an establishment that sells tobacco products and is located at 205 Bridge Street, Phoenixville, Pennsylvania 19460. Complaint ¶¶ 6-7.
- During an inspection of Respondent's establishment on June 15, 2015, at approximately 12:49 PM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes . . . [.]" The inspector also observed that "the minor's identification was not verified before the sale . . . ." Complaint ¶ 10.
- On July 16, 2015, CTP issued a Warning Letter to Respondent regarding the inspector's observations from June 15, 2015. The letter explained that the observations constituted violations of regulations, and that the named violations were 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 violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶¶ 10-11.

- During a subsequent inspection of Respondent’s establishment on June 15, 2016, at approximately 1:26 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]” Complaint ¶ 8.

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); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). The regulations prohibit the sale of cigarettes 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 cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i).

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)(1), on June 15, 2015, and on June 15, 2016. On June 15, 2015, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

### **ORDER**

For these reasons, I grant Complainant’s Motion to Impose Sanctions, strike Respondent’s answer, and enter default judgment in the amount of \$275 against Respondent, V-12 Variety Store LLC, d/b/a Steal Deal Apparel and Gift Shop. 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/  
Bill Thomas  
Administrative Law Judge