

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-4151)

Complainant

v.

Sawa Tobacco, Inc.
d/b/a Orlando Cigar and Tobacco Shop,

Respondent.

Docket No. T-17-1034

Decision No. TB1650

Date July 17, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Sawa Tobacco, Inc. d/b/a Orlando Cigar and Tobacco Shop, located at 5326 Central Florida Parkway, Orlando, Florida 32821, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Orlando Cigar and Tobacco Shop impermissibly sold cigarettes 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. CTP seeks to impose a \$550 civil money penalty against Respondent Orlando Cigar and Tobacco Shop. During the course of this administrative proceeding, Respondent has failed to comply with two separate judicial directions regarding CTP's discovery request. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

CTP began this matter by serving an administrative complaint, seeking a \$550 civil money penalty, on Respondent Sawa Tobacco, Inc. d/b/a Orlando Cigar and Tobacco Shop at 5326 Central Florida Parkway, Orlando, Florida 32821. Respondent filed an answer to CTP's complaint on January 4, 2017. I issued an Acknowledgement and Prehearing Order (APHO) on February 1, 2017, that set deadlines for parties' submissions, including the March 3, 2017 deadline to request that the opposing party provide copies of documents relevant to this case. Additionally, the APHO stated that a party receiving such a request must provide the requested documents no later than 30 days after the request. CTP served Respondent with its request for documents on March 3, 2017.

On April 11, 2017, CTP filed a Motion to Compel Discovery indicating that Respondent did not respond to its request within the time limit. *See* 21 C.F.R. § 17.23(a). On the same date, CTP also filed a motion requesting that all pre-hearing exchange deadlines be extended for 30 days. In an April 12, 2017 letter issued by my direction, I extended the parties' exchange deadlines and gave Respondent until April 27, 2017, to object to CTP's motion. Respondent did not file an objection to CTP's motion.

In a May 4, 2017 Order, I granted CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines. The Order allowed Respondent until May 25, 2017 to comply with CTP's discovery request. In granting CTP's Motion to Compel Discovery, I explained 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. CTP subsequently filed a Motion to Impose Sanctions on May 26, 2017, indicating that Respondent did not comply with the Order Granting CTP's Motion to Compel. On the same date, CTP also filed a motion requesting that all pre-hearing exchange deadlines be extended for 30 days. In a May 31, 2017 letter issued by my direction, I extended the parties' exchange deadlines, and Respondent was given until June 15, 2017, to object to CTP's motion. To date, Respondent has not filed a response to CTP's Motion to Impose Sanctions.

II. Striking Respondent's Answer

On May 26, 2017, CTP filed a Motion to Impose Sanctions. In its May 26, 2017 Motion to Impose Sanctions, CTP stated that "Respondent has neither produced any of the requested documents, nor contacted Complainant or Counsel regarding this matter." Respondent filed no response to CTP's Motion to Impose Sanctions.

Due to noncompliance with my Acknowledgement and Pre-Hearing Order (APHO) and my Order granting CTP's Motion to Compel, I am striking Respondent's answer, issuing

this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. §§ 17.35(a)(1), (c)(3), 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).

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:

- Respondent owns Orlando Cigar and Tobacco Shop, an establishment that sells tobacco products and is located at 5326 Central Florida Parkway, Orlando, Florida 32821. Complaint ¶¶ 6-7.
- During an inspection of Respondent's establishment on February 6, 2016, at approximately 11:13 AM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Pall Mall Orange cigarettes . . . [.]" Complaint ¶ 10.
- On February 25, 2016, CTP issued a Warning Letter to Respondent regarding the inspector's observation from February 6, 2016. The letter explained that the observation constituted a violation of regulations, 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 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 May 21, 2016, at approximately 1:04 PM, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of American Spirit Natural Orange cigarettes . . . [.]" The inspector also documented that "the minor's identification was not verified before the sale" Complaint ¶ 8.

These facts establish Respondent Orlando Cigar and Tobacco Shop’s liability 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 February 6, 2016, and May 21, 2016. On May 21, 2016, 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 enter default judgment in the amount of \$550 against Respondent Sawa Tobacco, Inc. d/b/a Orlando Cigar and Tobacco 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/
Steven T. Kessel
Administrative Law Judge