

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

SSSAH123 Inc.
d/b/a Austintown Beverage Center,

Respondent.

Docket No. T-19-409
FDA No. FDA-2018-H-4200

Decision No. TB3955

Date: June 7, 2019

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

The Center for Tobacco Products (CTP) began this case by serving the Complaint on Respondent, SSSAH123 Inc. d/b/a Austintown Beverage Center, and filing a copy of the Complaint with the Civil Remedies Division (CRD). The Complaint alleges that Respondent impermissibly sold cigarettes and a covered tobacco product to minors and failed to verify that the covered tobacco product purchaser was 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, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$559 against the Respondent for three violations of the tobacco regulations within a 24-month period. Respondent requested a hearing by filing an Answer, which denied all allegations of liability and the appropriateness of the civil money penalty.

Currently, Complainant's Status Report and Motion to Impose Sanctions ("Motion to Impose Sanctions") is pending before me. CTP's Motion to Impose Sanctions requests that I strike Respondent's Answer as a sanction for failing to comply with CTP's discovery requests and issue a default judgment against Respondent. For the reasons stated below, I grant CTP's Motion to Impose Sanctions, strike the Respondent's Answer, and issue an initial decision and default judgment imposing a civil money penalty in the amount of \$559 against Respondent. 21 C.F.R. § 17.35(c)(3).

I. Background and Procedural History

As provided in 21 C.F.R. §§ 17.5 and 17.7, CTP served the complaint on Respondent Austintown Beverage Center by United Parcel Service on November 6, 2018.¹ On November 25, 2018, Respondent filed the first page of the Complaint twice via the Departmental Appeals Board Electronic Case Filing (DAB E-File) system. On December 7, 2018, Respondent's owner indicated that she had difficulty uploading the Answer to DAB E-File and had sent the Answer by United States Postal Service. By letter dated December 11, 2018, I granted a 3-week extension for Respondent to file an answer that complied with the regulations. *See* 21 C.F.R. § 17.9. Respondent timely filed its Answer, which the CRD received on December 12, 2018.

On December 21, 2018, I issued an Acknowledgment and Pre-Hearing Order (APHO) acknowledging receipt of Respondent's Answer and establishing procedural deadlines for this case. The APHO set a deadline of January 22, 2019, for the parties to request documents from the opposing party and explained that a party must provide the requested documents no later than 30 days after the request has been made, pursuant to 21 C.F.R. § 17.23(a). APHO ¶ 12. The APHO also stated that a party may file a motion for a protective order within 10 days of receiving a request for the production of documents. *Id.*; 21 C.F.R. §§ 17.23(d), 17.28. Additionally, the APHO ordered the parties to file a joint status report within 30 days, ordered CTP to file its pre-hearing exchange by March 12, 2019, and ordered Respondent to file its pre-hearing exchange by April 2, 2019. APHO ¶¶ 3-4. Further, the APHO warned the parties that "I may impose sanctions including, but not limited to, dismissal of the complaint or answer, if a party fails to comply with any order (including this order), fails to prosecute or defend its case, or

¹ The UPS Delivery Notification indicates that the Complaint was delivered to "4903 Mahoning Ave, Youngstown, OH 44515," while the Complaint states that Respondent's address is "4903 Mahoning Avenue, Austintown, OH 44515." CTP did not amend its Complaint to conform with the proof of service. Nevertheless, I find that the Respondent has received proper service of the Complaint as evidenced by the filing of its Answer. I note that this decision has been delivered to both addresses listed in the Complaint and the UPS Delivery Notification with instructions on how to file a motion to reopen if the Respondent believes this decision was entered in error.

engages in misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.” APHO ¶ 16; *see also* 21 C.F.R. § 17.35.

On January 22, 2019, CTP served a timely Request for Production of Documents on Respondent. On February 28, 2019, CTP filed a Motion to Compel Discovery stating that it had not received a response to its Request for Production of Documents and requesting “an order be entered compelling Respondent to respond to CTP’s Request for Production of Documents in its entirety.”

In a March 1, 2019 letter issued by my direction, Respondent was given until March 15, 2019, to file a response to CTP’s Motion to Compel Discovery. Also, the pre-hearing exchange deadlines were extended by 30 days in a March 1, 2019 Order. Respondent did not file a response to CTP’s Motion to Compel Discovery or otherwise respond to the letter or Order issued on March 1, 2019. Therefore, in a March 20, 2019 Order, I granted CTP’s motion and ordered Respondent to comply with CTP’s Request for Production of Documents by April 5, 2019. I also further extended the parties’ pre-hearing exchange deadlines by 30 days. I warned Respondent that a failure to comply might 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.

On April 11, 2019, CTP filed a Motion to Impose Sanctions stating, “Respondent has not produced documents to CTP in response to its [Request for Production of Documents].” CTP requested I strike Respondent’s Answer and issue a default judgment imposing a civil money penalty in the amount of \$559 against Respondent. In an April 15, 2019 Order, I gave Respondent until April 26, 2019, to file a response to CTP’s Motion to Impose Sanctions and extended the pre-hearing exchange deadlines by 30 days. To date, Respondent has not filed a response to CTP’s Motion to Impose Sanctions or the April 15, 2019 Order. CTP’s Motion to Impose Sanctions is now ripe for a ruling.

II. Sanctions

The regulations authorize me to impose sanctions on any party or counsel for:

- (1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;
- (2) Failing to prosecute or defend an action; or
- (3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

21 C.F.R. § 17.35(a). When a party “fails to comply with a discovery order,” I may draw an inference in favor of the opposing party, may prohibit the non-complying party from introducing or relying on evidence related to the discovery request, and may “[s]trike any

part of the pleadings or other submissions of the party failing to comply with [the discovery] request.” 21 C.F.R. § 17.35(c). Any sanction “shall reasonably relate to the severity and nature of the failure or misconduct.” 21 C.F.R. § 17.35(b).

I conclude that sanctions against Respondent are warranted. During the course of this administrative proceeding, Respondent repeatedly failed to comply with multiple orders, letters containing judicial directives, and procedures governing this proceeding. As such, Respondent has failed to defend this action, which has interfered with the speedy, orderly, and fair conduct of this proceeding. 21 C.F.R. § 17.35(a). Specifically, Respondent failed to comply with the discovery requirements of the applicable regulations and my December 21, 2018 APHO, both of which require the parties to produce documents within 30 days of a discovery request or to seek a protective order.² 21 C.F.R. § 17.23(a); APHO ¶ 12. Respondent has not provided the requested documents or requested a protective order. Additionally, Respondent did not file a response to CTP’s Motion to Compel Discovery, as required by the regulations, my March 1, 2019 Order, and a March 1, 2019 letter issued by my direction. 21 C.F.R. § 17.32(c). Respondent also failed to comply with the March 20, 2019 Order granting CTP’s Motion to Compel Discovery, which required Respondent to produce documents by April 5, 2019. Furthermore, Respondent did not respond to CTP’s Motion to Impose Sanctions, again in contravention of the regulations and the April 15, 2019 Order.

In the absence of any explanation from Respondent, I find no basis to excuse Respondent’s repeated failure to comply with the various orders, judicial directives, and regulations in this proceeding. Despite explicit warnings that its failure to comply with the orders could result in sanctions, Respondent did not comply with four orders that I issued in this case. Likewise, Respondent did not comply with the directives in the March 1, 2019 letter issued by my direction. Further, Respondent did not respond to any of CTP’s motions. Accordingly, I find that Respondent failed to comply with orders and procedures governing this proceeding, failed to defend its case, and, as a result, engaged in a pattern of misconduct that interfered with the speedy, orderly, and fair conduct of the hearing. Notably, Respondent’s failure to comply with orders and regulations governing discovery and other procedures in this case necessitated extending the pre-hearing exchange deadlines three times, which delayed the hearing. *See* March 1, 2019 Order; March 20, 2019 Order; and April 15, 2019 Order. As the Departmental Appeals Board has recognized in a similar case involving a party’s failure to comply with discovery orders, this conduct is sufficiently egregious to warrant striking Respondent’s Answer and issuing an initial decision by default. *See, e.g., KKNJ, Inc. d/b/a Tobacco Hut 12,*

² Respondent also failed to comply with the status report requirements of the APHO, which required the parties to submit a joint status report regarding the status of settlement negotiations. APHO ¶ 3. According to CTP’s Status Report, filed on January 22, 2019, CTP was unable to reach Respondent to finalize a settlement and Respondent did not join in the Status Report.

DAB No. 2678, at 10 (2016) (concluding that “the ALJ did not abuse her discretion in sanctioning Respondent’s ongoing failure to comply with the ALJ’s directions by striking Respondent’s answer to the Complaint”). Therefore, pursuant to 21 C.F.R. §§ 17.35(a) and (c)(3), I grant CTP’s Motion to Impose Sanctions, and strike Respondent’s Answer for failing to comply with numerous orders, judicial directives, and procedures governing this proceeding, failing to defend this action, and engaging in a pattern of misconduct that has interfered with the speedy, orderly, and fair conduct of the hearing.

III. Default Decision

Striking Respondent’s Answer leaves the Complaint unanswered. 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 Austintown Beverage Center, an establishment that sells tobacco products and is located at 4903 Mahoning Avenue, Austintown, Ohio 44515. Complaint ¶¶ 7-8.
- During an inspection of Respondent’s establishment on April 15, 2017, at approximately 2:24 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes” Complaint ¶¶ 11-12.
- On April 27, 2017, CTP issued a Warning Letter to Respondent regarding the documented violation from April 15, 2017. The letter explained that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter also stated 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 ¶ 12.
- During a subsequent inspection of Respondent’s establishment on August 16, 2018, at approximately 10:35 PM, “a person younger than 18 years of age was able to purchase a Black & Mild cigar . . .” and “the minor’s identification was not verified before the sale . . .” 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 also* 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 and covered tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(b)(1). The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no covered tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(2)(i).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes and covered tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(b)(1), on April 15, 2017, and August 16, 2018. On August 16, 2018, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no covered tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(2)(i). All violations observed during the initial failed inspection are counted as a single violation, and each separate violation observed during subsequent failed inspections count as a discrete violation. *Orton Motor, Inc., d/b/a Orton's Bagley v. U.S. Dep't of Health & Human Serv.*, 884 F.3d 1205 (D.C. Cir. 2018). Therefore, Respondent's actions constitute three violations of law within a 24-month period that merit a civil money penalty.

CTP has requested a civil money penalty of \$559, which is a permissible penalty under the regulations. 21 C.F.R. §§ 17.2, 17.11; *see also* 45 C.F.R. § 102.3. Therefore, I find that a civil money penalty of \$559 is warranted and so order one imposed.

/s/
Karen R. Robinson
Administrative Law Judge