

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-0459)

Complainant

v.

Aramex, LLC
d/b/a Ashe Street Convenience Store,

Respondent.

Docket No. T-18-1106

Decision No. TB2985

Date: August 10, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint (Complaint) on Aramex, LLC d/b/a Ashe Street Convenience Store (Respondent), at 63 Ashe Street, Charleston, South Carolina 29403, 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 cigarettes or smokeless tobacco 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 an \$11,182 civil money penalty against Respondent.

During the course of the administrative proceedings, Respondent failed to comply with orders and procedures governing this proceeding, has failed to defend its case, and, as a result, has interfered with the speedy, orderly, and fair conduct of this proceeding.

21 C.F.R. § 17.35(a). Accordingly, pursuant to 21 C.F.R. § 17.35(c)(3), I strike Respondent's Answer as a sanction and issue this decision of default judgment.

I. Procedural History

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on February 1, 2018, CTP served the Complaint on Respondent by United Parcel Service. On March 5, 2018, Respondent timely filed an Answer to the Complaint. On March 7, 2018, I issued an Acknowledgement and Pre-Hearing Order (APHO) in which I set deadlines for the parties' filings and exchanges, including a schedule for discovery. APHO ¶¶ 4, 12. I directed that a party receiving a discovery request must provide the requested documents within 30 days of the request and warned that I may impose sanctions if a party failed to comply with any order. APHO ¶¶ 4, 12, 16; *see* 21 C.F.R. §§ 17.23(a), 17.35.

In accordance with the deadlines set forth in the APHO, CTP served Respondent with its Request for Production of Documents on March 23, 2018. On May 22, 2018, CTP filed a Motion to Compel Discovery asserting that Respondent had not responded to its discovery request. By Order of May 23, 2018, I informed Respondent that it had until June 6, 2018, to file a response to CTP's Motion to Compel Discovery. *See* 21 C.F.R. § 17.32(c). Respondent did not respond.

Accordingly, on June 7, 2018, I issued an Order to Compel Discovery granting CTP's motion and ordering Respondent to comply with CTP's Request for Production of Documents by June 22, 2018. I warned Respondent that:

[F]ailure to comply may **result in sanctions**, which may include striking its Answer as a sanction and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty. 21 C.F.R. § 17.35.

June 7, 2018, Order to Compel Discovery (Emphasis in original).

On June 26, 2018, CTP filed a Motion to Impose Sanctions. CTP advised that Respondent had not complied with my Order to Compel Discovery. CTP requested that I strike Respondent's Answer and issue a default judgment in its favor. By Order of June 27, 2018, I informed Respondent that it had until July 5, 2018, to file a response to CTP's Motion to Impose Sanctions. I warned that if Respondent failed to file a response, "I may grant CTP's Motion to Impose Sanctions in its entirety." June 27, 2018 Order. Respondent did not respond.

II. Striking Respondent's Answer

I may sanction a party 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).

Respondent failed to comply with the following orders and procedures governing this proceeding:

- Respondent failed to comply with 21 C.F.R. § 17.23(a) and paragraph 12 of my APHO, when Respondent failed to respond to CTP's Request for Production of Documents within 30 days; and
- Respondent failed to comply with my June 7, 2018, Order to Compel Discovery, when it failed to submit the documents CTP requested by June 22, 2018.

Respondent failed to defend its action despite the following opportunities:

- By Order of May 23, 2018, I informed Respondent that it had until June 6, 2018, to file a response to CTP's Motion to Compel Discovery. Respondent did not defend its action; and
- By Order of June 27, 2018, I informed Respondent that it had until July 5, 2018, to file a response to CTP's Motion to Impose Sanctions. Respondent did not defend its action.

I find that Respondent has failed to comply with orders and procedures governing this proceeding, has failed to defend its case, and, as a result, has interfered with the speedy, orderly, and fair conduct of this proceeding. I conclude that Respondent's conduct establishes a basis for sanctions pursuant to 21 C.F.R. § 17.35, and that sanctions are warranted.

The harshness of the sanctions I impose must relate to the nature and severity of the misconduct or failure to comply. 21 C.F.R. § 17.35(b). Here, Respondent failed to comply with two of my orders, despite my explicit warning that its failure could result in sanctions. I specified that those sanctions may include striking its Answer and "issuing an Initial Decision and Default Judgment finding Respondent liable for the violations

listed in the Complaint and imposing a civil money penalty.” June 7, 2018, Order to Compel Discovery. Respondent also failed to defend its actions, despite my orders expressly reminding Respondent of the opportunity. I find that Respondent’s actions are sufficient to warrant striking its Answer and issuing a decision by default, without further proceedings. 21 C.F.R. § 17.35(b), (c)(3). Accordingly, I strike Respondent’s Answer, and issue this Initial Decision and Default Judgment, assuming the facts alleged in CTP’s Complaint to be true. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

III. Default Decision

Striking Respondent’s answer leaves the Complaint unanswered. Therefore, 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.

Specifically, CTP alleges the following facts in its Complaint:

- On September 8, 2015, CTP initiated a previous civil money penalty action, CRD Docket Number C-15-3656, FDA Docket Number FDA-2015-H-2857, against Respondent for three¹ violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred at Respondent’s business establishment, 63 Ashe Street, Charleston, South Carolina 29403, on May 22, 2014, September 22, 2014, and May 22, 2015;²
- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and agreed to pay a monetary penalty in settlement of that claim. Further, “Respondent expressly waived its right to contest such violations in subsequent actions”;
- At approximately 4:59 PM on March 16, 2017, at Respondent’s business establishment, 63 Ashe Street, Charleston, South Carolina 29403, an FDA-commissioned inspector documented Respondent’s staff selling a package of Newport Box cigarettes to a person younger than 18 years of age;
- In a warning letter dated June 29, 2017, CTP informed Respondent of the inspector’s March 16, 2017 documented violation, and that such action violates

¹ Two violations were documented on May 22, 2014 (sale to a minor and failure to verify identification), one on September 22, 2014 (sale to a minor), and one on May 22, 2015 (sale to a minor). In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

² See also FDA Docket Number FDA-2015-H-0488, CRD Docket Number C-15-1319.

federal law. The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action;

- At approximately 1:27 PM on January 9, 2018, at Respondent's business establishment, 63 Ashe Street, Charleston, South Carolina 29403, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro Gold Pack cigarettes to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

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. § 387f(d); *see* 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). Under 21 C.F.R. § 1140.14(a)(1),³ no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age.

An \$11,182 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$11,182 against Respondent Aramex, LLC d/b/a Ashe Street Convenience Store. 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/
Wallace Hubbard
Administrative Law Judge

³ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.