Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Washington Ave Convenient LLC d/b/a Convenient Food Mart,

Respondent.

Docket No. T-19-311 FDA No. FDA-2018-H-4080

Decision No. TB3707

Date: April 9, 2019

INITIAL DECISION AND DEFAULT JUDGMENT

I hereby impose a civil money penalty (CMP) in the amount of \$5,591, against Respondent, Washington Ave Convenient LLC d/b/a Convenient Food Mart (Respondent), for five violations of federal tobacco regulations over a period of 36-months.

I. Background

The Center for Tobacco Products (Complainant or CTP) seeks to impose a CMP in the amount of \$5,591, against Respondent, located at 33 Washington Avenue, Wheeling, West Virginia 26003, for five violations of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a 36-month period. The complaint alleges that Respondent impermissibly sold cigarettes to minors, failed to verify, by means of photo identification containing a date of birth, that one of the purchasers was 18 years of age or older, thereby violating the Act, and its implementing regulations at 21 C.F.R. pt. 1140. The complaint further alleges that an Initial Decision and Default Judgment was previously entered against Respondent Convenient Food Mart for two violations of regulations found at 21 C.F.R. pt. 1140 and,

therefore, CTP seeks a \$5,591 civil money penalty against Respondent Convenient Food Mart for five violations within a 36-month period.

As provided in 21 C.F.R. §§ 17.5 and 17.7, on October 30, 2018, Complainant served the complaint on Respondent Convenient Food Mart by United Parcel Service. Respondent timely filed its answer on November 29, 2018. Respondent admitted the allegations, but requested a penalty reduction as the company implemented new policies to prevent future violations. On November 29, 2018, I issued an Acknowledgment and Pre-hearing Order (APHO) acknowledging receipt of Respondent's answer and setting forth case procedures and deadlines. The APHO contained a provision that set out instructions regarding a party's request for production of documents. That provision states, in part, that a party had until January 7, 2019, to request the opposing party provide copies of documents relevant to this case. The order also stated that a party receiving such a request 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). The parties were warned that failure to comply with any order including the APHO may result in sanctions.

On January 17, 2019, Complainant filed a Motion to Compel Discovery stating that it sent its Request for Production of Documents to Respondent on December 12, 2018. Complainant also stated that it had not received a response from Respondent to its Request for Production of Documents and requested that I issue an order requiring Respondent to comply with Complainant's Request for Production of Documents. In a January 18, 2019 letter issued by my direction, Respondent was given until February 1, 2019, to file a response to Complainant's Motion to Compel Discovery.

Respondent failed to file a response to Complainant's Motion to Compel Discovery or the January 18, 2019 letter. Accordingly, in an order dated March 1, 2019, I granted Complainant's Motion to Compel Discovery and ordered Respondent to comply with Complainant's Request for Production of Documents by March 8, 2019. Respondent was warned that failure to do so may 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 penalty.

On March 14, 2019, Complainant filed a Status Report and Motion to Impose Sanctions indicating that Respondent had not complied with my March 1, 2019 order. Complainant requested I strike Respondent's answer and issue an initial decision and default judgment imposing a money penalty against Respondent. In a March 18, 2019 letter issued by my direction, Respondent was given until March 29, 2019, to file a response to Complainant's Motion to Impose Sanctions. To date, Respondent has not responded to Complainant's Motion to Impose Sanctions or the March 18, 2019 letter.

Therefore, pursuant to 21 C.F.R. § 17.35, I am granting Complainant's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with multiple judicial

orders and directives. Specifically, Respondent failed to comply with the deadline set forth in the APHO for responding to a discovery request, and the order granting Complainant's Motion to Compel Discovery issued on March 1, 2019. Respondent also did not respond to Complainant's Motion to Impose Sanctions or the letter sent by my direction on March 18, 2019. This repeated conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default.

II. <u>Default Decision</u>

Striking Respondent's answer leaves the complaint unanswered. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- On March 31, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-3084, FDA Docket Number FDA-2017-H-1793, against Respondent for two violations of 21 C.F.R. pt. 1140 within a 12-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 33 Washington Avenue, Wheeling, West Virginia 26003, on February 7, 2016, and October 20, 2016;
- The previous action concluded when an Initial Decision and Default Judgment was entered by an Administrative Law Judge, "finding that all of the violations alleged in the Complaint occurred";
- At approximately 6:33 PM on March 28, 2018, at Respondent's business establishment, 33 Washington Avenue, Wheeling, West Virginia 26003, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro 100's cigarettes to a person younger than 18 years of age;
- In a warning letter dated May 24, 2018, CTP informed Respondent of the inspector's March 28, 2018 documented violation, and that such action violates 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;
- During a subsequent inspection, at approximately 3:49 PM on August 6, 2018, at Respondent's business establishment, 33 Washington Avenue, Wheeling, West Virginia 26003, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro Special Blend 100's 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. § 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),¹ 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.

A \$5,591 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$5,591 against Respondent Washington Ave Convenient LLC d/b/a Convenient Food Mart. 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/
Catherine Ravinski
Administrative Law Judge

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¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: https://federalregister.gov/a/2016-10685.