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

Center for Tobacco Products,

Complainant,

v.

Jarbo and Abro, Inc. d/b/a Buscemis 5,

Respondent.

Docket No. T-19-362 FDA No. FDA-2018-H-4141

Decision No. TB3724

Date: April 12, 2019

#### INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Jarbo and Abro, Inc. d/b/a Buscemis 5, at 42990 Garfield Road, Clinton Township, Michigan 48038, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Buscemis 5 impermissibly sold cigarettes and covered tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, 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, 21 C.F.R. pt. 1140. CTP seeks a \$279 civil money penalty against Respondent Buscemis 5 for two violations within a 12-month period.

During the hearing process, Respondent failed to comply with judicial orders and directions. I, therefore, strike Respondent's answer and issue this decision of default judgment.

#### I. Background

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on November 2, 2018, CTP served the complaint on Respondent Buscemis 5 by United Parcel Service. On December 6, 2018, after Respondent's answer was filed, I issued an Acknowledgment and Pre-hearing Order (APHO) 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 that the other party provide copies of documents relevant to this case. The APHO also stated that, pursuant to 21 C.F.R. § 17.23(a), a party receiving such a request must provide the requested documents no later than 30 days after the request has been made. APHO ¶ 12. The parties were warned that failure to comply with any order including the APHO may result in sanctions. APHO ¶ 16.

On February 12, 2019, CTP filed a Motion to Compel Discovery stating that its request for production of documents (RFP) was served on Respondent on January 7, 2019. CTP further stated that it did not receive a response from Respondent regarding its RFP, and requested that I issue an order requiring Respondent to comply. In a February 13, 2019 letter issued by my direction, Respondent was given until February 27, 2019 to file a response to CTP's Motion to Compel Discovery. Respondent did not file a response to CTP's Motion to Compel Discovery or the February 13, 2019 letter. Therefore, on February 28, 2019, I granted CTP's Motion to Compel Discovery and ordered Respondent to comply with CTP's RFP by March 8, 2019. I warned Respondent that failure to comply with my order may result in sanctions, including the issuance of an initial decision and default judgment finding Respondent liable for the violations alleged in the complaint and imposing a civil money penalty.

On March 15, 2019, CTP filed a Status Report and Motion to Impose Sanctions stating that Respondent had not produced documents in response to CTP's RFP as ordered. CTP requested I strike Respondent's answer and issue an initial decision and default judgment imposing a civil money penalty against Respondent. In a March 19, 2019 letter issued by my direction, Respondent was given until April 1, 2019 to file a response to CTP's Motion to Impose Sanctions. To date, Respondent has not responded to the Motion to Impose Sanctions or the March 19, 2019 letter.

Therefore, pursuant to 21 C.F.R. § 17.35, I grant CTP's Motion to Impose Sanctions, and strike Respondent's answer for failing to comply with multiple judicial orders and directions. Specifically, Respondent failed to comply with my December 6, 2018 APHO requiring it to respond to CTP's RFP within 30 days after the request has been made, and my February 28, 2019 order requiring it to respond to CTP's RFP by March 8, 2019. Additionally, Respondent failed to respond to CTP's Motion to Compel Discovery, CTP's Motion to Impose Sanctions, or the February 13, 2019 and March 19, 2019 letters

issued by my direction. 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:

- At approximately 7:35 PM on January 8, 2018, at Respondent's business establishment, 42990 Garfield Road, Clinton Township, Michigan 48038, an FDA-commissioned inspector documented Respondent's staff selling a package of two Swisher Sweets Tropical Fusion cigars 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;
- In a warning letter dated January 25, 2018, CTP informed Respondent of the inspector's January 8, 2018 documented violations, and that such actions violated federal law. The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 12:45 PM on August 24, 2018, at Respondent's business establishment, 42990 Garfield Road, Clinton Township, Michigan 48038, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age.

These facts establish Respondent Buscemis 5'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 sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); see also 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). Under 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(b)(1), no retailer may sell cigarettes or covered tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no covered tobacco product purchasers are younger than 18 years of age.

Under 21 C.F.R. § 17.2, a \$279 civil money penalty is permissible for two violations of the regulations found at 21 C.F.R. pt. 1140 within a 12-month period.

# Order

For these reasons, I enter default judgment in the amount of \$279 against Respondent Jarbo and Abro, Inc. d/b/a Buscemis 5. 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