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

Center for Tobacco Products,

Complainant,

v.

Kira-Dhar, Inc. d/b/a Tiger Mart / Exxon,

Respondent.

Docket No. T-19-95 FDA No. FDA-2018-H-3824

Decision No. TB3676

Date: April 4, 2019

#### INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Kira-Dhar, Inc. d/b/a Tiger Mart / Exxon, at 6040 State Route 35, South Amboy, New Jersey 08879, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Tiger Mart / Exxon impermissibly sold cigarettes to a minor and failed to verify, by means of photo identification containing a date of birth, that the 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. The complaint also alleges that Respondent previously sold cigarettes or smokeless tobacco products 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. The complaint further alleges that Respondent Tiger Mart / Exxon previously admitted to five violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose an \$11,182 civil money penalty against Respondent Tiger Mart / Exxon for seven violations within a 48-month period.

During the hearing process, Respondent failed to comply with judicial orders. 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 October 11, 2018, CTP served the complaint on Respondent Tiger Mart / Exxon by United Parcel Service. Kiran Patel registered for the Departmental Appeals Board Electronic Case Filing (DAB E-File) system and timely filed an answer on behalf of Respondent. In its answer, Respondent admitted the complaint allegations and requested a reduction of the civil money penalty.

On November 14, 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 filing of the parties' pre-hearing exchanges. That provision states, in part, that CTP shall file its pre-hearing exchange by February 4, 2019, and Respondent shall file its pre-hearing exchange by February 25, 2019. The APHO also warned that failure to comply with any order including the APHO may result in sanctions. The APHO was served on Respondent via DAB E-File.

On February 4, 2019, CTP, through counsel, timely filed its pre-hearing exchange. Respondent, however, failed to file its pre-hearing exchange by the February 25, 2019 deadline established by the APHO or any time thereafter. To date, Respondent provided no explanation for its failure to file its pre-hearing exchange.

On February 28, 2019, I issued an order scheduling a pre-hearing conference for March 12, 2019, at 11:00 AM Eastern Time. The parties were provided with a call-in telephone number and passcode. The February 28, 2019 order was served on Respondent via DAB E-File.

On March 12, 2019, I held a pre-hearing conference. Respondent failed to appear at the pre-hearing conference call and provided no response to the February 28, 2019 order.

On March 12, 2019, I issued an Order allowing Respondent until March 19, 2019 to show cause for its failure to appear at the March 12, 2019 pre-hearing conference. I warned Respondent that failure to show cause 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. The March 12, 2019 order was served on Respondent via DAB E-File.

On March 15, 2019, Respondent filed a letter addressed to CTP's counsel and signed by Mr. Patel. The letter stated Mr. Patel was "out of country from January 19, 2019 through February 27, 2019 and didn't have access to [his] work email." The letter further

explained that when Mr. Patel "returned back to work on March 13, 2019, [he] learn[ed] about the prehearing conference call on this case but it was too late." Respondent, however, provided no evidence confirming Mr. Patel was out of the country or had no access to his work email between January 19, 2019, and February 27, 2019. Moreover, Respondent failed to explain what precluded Mr. Patel from checking his work email upon his return to the country on February 27, 2019. Indeed, the order scheduling prehearing conference was issued on February 28, 2019, meaning Mr. Patel had almost two weeks to check his email but failed to do so. Still further, even though Mr. Patel claimed having no access to his work email, he provided no explanation for being unable to check the DAB E-File system for the up-to-date filings in this case.

### II. Striking Respondent's Answer

Pursuant to 21 C.F.R. § 17.35(a)(1), I may sanction a party for failing to comply with an order, subpoena, rule, or procedure governing the proceeding. As outlined above, Respondent failed to comply with my November 14, 2018 APHO and my February 28, 2019 order. Specifically, Respondent failed to file its pre-hearing exchange by the February 25, 2019 deadline established by the APHO, and provided no explanation for its failure to do so. Still further, Respondent failed to appear at the pre-hearing conference call scheduled by the February 28, 2019 order. Although Respondent submitted a response to the March 12, 2019 show cause order, I find the response insufficient to show good cause for Respondent's failure to appear at the March 12, 2019 pre-hearing conference call. Accordingly, I find that Respondent failed to comply with my orders and has not established good cause for failure to comply with my orders.

The conduct of Respondent in connection with the proceedings in this case since the answer was filed warrants sanctions. 21 C.F.R. § 17.35(a)(1). 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). I find Respondent's repeated conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default.

#### III. <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 June 13, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-4547, FDA Docket Number FDA-2017-H-3407, against

Respondent for five<sup>1</sup> violations of 21 C.F.R. pt. 1140 within a 36-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 6040 State Route 35, South Amboy, New Jersey 08879, on July 5, 2015, December 12, 2015, and March 18, 2017;

- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";
- At approximately 4:25 PM on July 18, 2018, at Respondent's business establishment, 6040 State Route 35, South Amboy, New Jersey 08879, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro 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 Respondent Tiger Mart / Exxon'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),² 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.

Under 21 C.F.R. § 17.2, an \$11,182 civil money penalty is permissible for seven violations of the regulations found at 21 C.F.R. pt. 1140 within a 48-month period.

<sup>&</sup>lt;sup>1</sup> Two violations were documented on July 5, 2015, two on December 12, 2015, and two on March 18, 2017. *See also* CRD Docket Number T-16-864, FDA Docket Number FDA-2016-H-1522. 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.

<sup>&</sup>lt;sup>2</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <a href="https://federalregister.gov/a/2016-10685">https://federalregister.gov/a/2016-10685</a>.

# Order

For these reasons, I enter default judgment in the amount of \$11,182 against Respondent Kira-Dhar, Inc. d/b/a Tiger Mart / Exxon. 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.

\_\_\_\_\_\_ Catherine Ravinski Administrative Law Judge