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

Center for Tobacco Products,

Complainant,

v.

Oasis Petro Inc. d/b/a BP,

Respondent.

Docket No. T-18-3596 FDA No. FDA-2018-H-3619

Decision No. TB3652

Date: March 26, 2019

#### INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Oasis Petro Inc. d/b/a BP, at 4276 West Fort Street, Detroit, Michigan 48209, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that BP impermissibly sold a covered tobacco product 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 an Initial Decision and Default Judgment was previously entered against Respondent BP for 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 BP for seven violations within a 48-month period.

During the hearing process, Respondent failed to comply with two judicial orders regarding CTP's discovery request. 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 September 27, 2018, CTP served the complaint on Respondent BP by United Parcel Service. Respondent, through counsel, timely filed an answer, in which, Respondent requested this matter to be dismissed.

On October 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 December 7, 2018, 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. The parties were warned that failure to comply with any order including the APHO may result in sanctions.

On January 10, 2019, CTP filed a Motion to Compel Discovery stating that its request for production of documents (RFP) was delivered to Respondent on November 29, 2018. 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. Respondent did not file a response to CTP's Motion to Compel Discovery. Therefore, on January 31, 2019, I granted CTP's Motion to Compel Discovery and ordered Respondent to comply with CTP's RFP by February 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 February 12, 2019, CTP filed a Status Report and Motion to Impose Sanctions stating that Respondent has not produced any documents 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 February 13, 2019 letter issued by my direction, Respondent was given until February 27, 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 to the February 13, 2019 letter.

Therefore, pursuant to 21 C.F.R. § 17.35, I am granting CTP's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with two separate judicial orders. Specifically, Respondent failed to comply with my October 29, 2018 APHO and my January 31, 2019 order requiring it to respond to CTP's RFP. Additionally, Respondent failed to respond to CTP's Motion to Impose Sanctions or the February 13, 2019 letter. This repeated conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default.

## **II.** Default Decision

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 April 21, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-3472, FDA Docket Number FDA-2017-H-2228, 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, 4276 West Fort Street, Detroit, Michigan 48209, on January 17, 2015, November 28, 2015, and November 12, 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 7:02 p.m. on July 11, 2018, at Respondent's business establishment, 4276 West Fort Street, Detroit, Michigan 48209, an FDA-commissioned inspector documented Respondent's staff selling a blu Classic Tobacco electronic nicotine delivery system (ENDS) product 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 BP'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 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) and 21 C.F.R. § 1140.14(b)(1),² no retailer may sell cigarettes, smokeless tobacco, or covered tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i) and 21 C.F.R. § 1140.14(b)(2)(i), retailers must verify, by means of photographic identification

<sup>&</sup>lt;sup>1</sup> One violation was documented on January 17, 2015, two on November 28, 2015, and two on November 12, 2016. *See also* CRD Docket Number T-16-533, FDA Docket Number FDA-2016-H-1032.

<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>.

containing a purchaser's date of birth, that no cigarette, smokeless tobacco, or covered tobacco product 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.

#### **Order**

For these reasons, I enter default judgment in the amount of \$11,182 against Respondent Oasis Petro Inc. d/b/a BP. 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/

Margaret G. Brakebusch Administrative Law Judge