

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-2166)

Complainant

v.

Bruce Express One Stop Inc.
d/b/a Bruce Express,

Respondent.

Docket No. T-16-1414

Decision No. TB1196

Date: April 25, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Bruce Express One Stop Inc. d/b/a Bruce Express, at 234 South Pontotoc Road, Bruce, Mississippi 38915, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Bruce Express impermissibly sold cigarettes 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 a \$550 civil money penalty against Respondent Bruce Express.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 2, 2016, CTP served the complaint on Bruce Express by United Parcel Service. In the complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time in which to file an answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, the

Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

I. Procedural History

On October 2, 2016, Respondent requested an extension of time to file an answer. The request was granted. On November 2, 2016, Respondent timely filed an answer to CTP's complaint. On November 4, 2016, I issued an Acknowledgment and Pre-hearing Order (APHO) that 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 5, 2016, to request that the other 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).

On December 5, 2016, CTP served its Request for Production of Documents on Respondent. On January 13, 2017, CTP filed a Motion to Compel Discovery stating it had not received a response from Respondent regarding its Request for Production of Documents. In a February 6, 2017 letter issued by my direction, Respondent was given until February 21, 2017 to file a response to CTP's Motion to Compel Discovery.

Respondent failed to respond to my February 6, 2017 letter. Therefore, on February 27, 2017, I granted CTP's Motion to Compel Discovery, and ordered Respondent to comply with CTP's discovery request by March 6, 2017. Respondent was warned that failure to comply with CTP's discovery request could 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 civil money penalty.

On March 15, 2017, CTP filed a Motion to Impose Sanctions indicating that Respondent has not complied with my February 27, 2017 order. On April 5, 2017, I issued an order requiring Respondent to show cause for (1) its failure to respond to CTP's discovery request as directed in my February 27, 2017 order, and (2) reasons why CTP's Motion to Impose Sanctions should not be granted. Respondent was given until April 20, 2017 to respond to my April 5, 2017 order. Respondent was again warned that failure to respond may result in sanctions, including striking the answer/request for hearing, and issuing a default judgment. To date, Respondent has not responded to my order.

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 four separate judicial directions, specifically the deadline set forth in the APHO for responding to any discovery request, the letter sent at my direction on February 6, 2017, the order granting CTP's motion to compel discovery issued on February 27, 2017, and finally the order to

show cause issued on April 5, 2017. 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:

- At approximately 10:24 a.m. on November 24, 2014, at Respondent's business establishment, 234 South Pontotoc Road, Bruce, Mississippi 38915, an FDA-commissioned inspector observed Respondent's staff selling a package of Marlboro Menthol cigarettes to a person younger than 18 years of age. The inspector also observed 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 December 30, 2014, CTP informed Respondent of the inspector's November 24, 2014 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). 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 4:15 p.m. on January 19, 2016, at Respondent's business establishment, 234 South Pontotoc Road, Bruce, Mississippi 38915, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Non-Menthol Box 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 Bruce Express'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)¹, no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R.

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

§ 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.

A \$550 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$550 against Respondent Bruce Express One Stop Inc. d/b/a Bruce Express. 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