

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-1590)

Complainant

v.

B and B Business Consulting, Inc.
d/b/a Bassfield Service Center,

Respondent.

Docket No. T-16-936

Decision No. TB788

Date: January 30, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, B and B Business Consulting, Inc. d/b/a Bassfield Service Center, located at 1754 Highway 35, Bassfield, Mississippi 39421, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Bassfield Service Center impermissibly sold 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, 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 \$500 civil money penalty against Respondent Bassfield Service Center. During the hearing process, Respondent has failed to comply with judicial directions and failed to appear for a pre-hearing conference. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

CTP began this matter by serving an administrative complaint, seeking a \$500 civil money penalty, on Respondent B and B Business Consulting, Inc. d/b/a Bassfield Service Center, at 1754 Highway 35, Bassfield, Mississippi 39421. Respondent filed an answer to CTP's complaint on July 14, 2016. I issued an Acknowledgement and Prehearing Order (APHO) on July 15, 2016, that set deadlines for the parties' submissions including the discovery deadlines.

On December 2, 2016, I issued an order scheduling a telephone pre-hearing conference. The conference was scheduled for January 6, 2017, at 10:00 AM Eastern Time. The parties were provided with a call in telephone number and passcode. However, Respondent did not appear at the pre-hearing conference call or otherwise provide any response to the Order that scheduled the pre-hearing conference.

On January 6, 2017, I issued an Order giving Respondent until January 23, 2017 to show cause for its failure to appear at the pre-hearing conference. The Order was electronically served on Respondent and a copy was mailed to its registered agent. Respondent was informed that failure to respond to the Order could result in sanctions including the issuance of a default judgment. As of the date of this Decision, a response to the Order has not been received.

II. Striking Respondent's Answer

Due to noncompliance with my Acknowledgement and Pre-Hearing Order (APHO) and my January 6, 2017 Order, as well as the failure to appear at the January 6, 2017 pre-hearing conference call, I am striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. §§ 17.35(a)(1), 17.35(c) (3), 17.11(a). The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and I find the failure to comply here sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

III. Default Decision

Striking Respondent's Answer leaves the Complaint unanswered. Therefore, I am required to issue an initial decision by default if the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true and conclude the default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with the orders. 21 C.F.R.

§ 17.11. Specifically:

- At approximately 11:06 a.m. on December 22, 2014, at Respondent's business establishment, 1754 Highway 35, Bassfield, Mississippi 39421, an FDA-commissioned inspector observed Respondent's staff selling a package of Marlboro 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 January 29, 2015, CTP informed Respondent of the inspector's December 22, 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 10:32 a.m. on December 17, 2015, at Respondent's business establishment, 1754 Highway 35, Bassfield, Mississippi 39421, FDA-commissioned inspectors documented Respondent's staff selling a package of Marlboro Red Label cigarettes to a person younger than 18 years of age. The inspectors 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 Bassfield Service Center'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, 28975-76 (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. § 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 \$500 civil money penalty is permissible under 21 C.F.R. § 17.2.

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

