

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-4218)

Complainant

v.

Paul Mcentire
d/b/a Paul's Place,

Respondent.

Docket No. T-17-1089

Decision No. TB1961

Date: September 26, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Paul Mcentire d/b/a Paul's Place, located at 3120 Carter Road, Ardmore, Oklahoma 73401, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Paul's Place impermissibly sold cigarettes and smokeless tobacco 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 Paul's Place. 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 on December 19, 2016, by serving an administrative complaint, seeking a \$550 civil money penalty, on Respondent Paul Mcentire d/b/a Paul's Place, at 3120 Carter Road, Ardmore, Oklahoma 73401. Respondent's answer to CTP's complaint was uploaded on January 17, 2017. I issued an Acknowledgement and Prehearing Order (APHO) on January 18, 2017, that set deadlines for the parties' submissions including the discovery deadlines. Throughout this case, multiple status reports and notices of pending settlement were filed. However, on June 8, 2017, CTP filed an updated status report indicating that settlement discussions had broken down and requesting an additional thirty (30) day extension of the pre-hearing deadlines. The request was granted on June 8, 2017. As a result, CTP's pre-hearing exchange was due on July 10, 2017, and Respondent's was due on July 31, 2017. CTP filed its exchange on July 10, 2017. Respondent did not file an exchange.

On August 1, 2017, I issued an order scheduling a telephone pre-hearing conference. The conference was scheduled for August 28, 2017, at 1:00 PM 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 August 29, 2017, I issued an Order giving Respondent until September 12, 2017 to show cause for its failure to appear at the pre-hearing conference. 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), failure to appear for the August 28, 2017 pre-hearing conference call, and failure to respond to my August 29, 2017 Show Cause Order, 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 5:17 p.m. on January 26, 2016, at Respondent's business establishment, 3120 Carter Road, Ardmore, Oklahoma 73401, an FDA-commissioned inspector documented Respondent's staff selling a package of Copenhagen Long Cut smokeless tobacco 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 February 4, 2016, CTP informed Respondent of the inspector's January 26, 2016 documentations, and that such actions violate 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 9:46 a.m. on May 25, 2016, at Respondent's business establishment, 3120 Carter Road, Ardmore, Oklahoma 73401, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro 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 Paul's Place'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 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

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

