

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-2912)

Complainant,

v.

Albert S. Fox
d/b/a Bottle Shop,

Respondent.

Docket No. C-15-3706

Decision No. CR4590

Date: April 19, 2016

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Albert S. Fox d/b/a Bottle Shop, located at 100 North Courtland Street, Chamberlain, South Dakota 57325, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Bottle Shop 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 \$500 civil money penalty against Respondent Bottle Shop. During the hearing process, Respondent has failed to comply with two separate judicial directions regarding CTP's discovery request, and has now also failed to comply with a third judicial order to submit its pre-hearing exchange date by April 11, 2016. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

CTP began this matter on August 27, 2015 by serving an administrative complaint seeking a \$500 civil money penalty on Respondent Bottle Shop, at 100 North Courtland Street, Chamberlain, South Dakota 57325. Respondent timely filed an answer to CTP's complaint on September 25, 2015. Administrative Law Judge Diane Townsend-Anderson issued an Acknowledgement and Prehearing Order (APHO) on October 15, 2015, that set deadlines for parties' submissions, including the November 16, 2015 deadline to request that the opposing party provide copies of documents relevant to this case. Additionally, the APHO stated that a party receiving such a request must provide the requested documents no later than 30 days after the request.

CTP served Respondent with its request for documents on November 16, 2015. On December 22, 2015, CTP filed a Motion to Compel Discovery indicating that Respondent did not respond to its request within the time limit. *See* 21 C.F.R. § 17.23(a). On the same date, CTP also filed a motion requesting that all pre-hearing exchange deadlines be extended. In a December 22, 2015 letter issued under the direction of Judge Townsend-Anderson, Respondent was given until January 6, 2016, to object to CTP's motion. On December 22, 2015, Judge Townsend-Anderson also extended the parties' pre-hearing exchange deadlines.

On January 14, 2016, the case was reassigned to Administrative Law Judge Steven T. Kessel. On February 19, 2016, Judge Kessel issued an order granting CTP's Motion to Compel Discovery and again extending the pre-hearing exchange deadlines. The Order gave Respondent until March 9, 2016 to comply with CTP's discovery request. Judge Kessel stated in the Order that:

Failure to do so may 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. Within five (5) days of Respondent's deadline to comply with discovery, CTP must file a status report notifying me whether Respondent has complied with discovery.

On March 14, 2016, CTP filed an Updated Status Report and a Motion to Impose Sanctions advising that Respondent had not complied with Judge Kessel's February 19, 2016 Order. In its Updated Status Report, CTP asked that any existing deadlines be extended.¹ In its Motion to Impose Sanctions, CTP asked that Respondent's answer be

¹ As I am issuing a default decision, it is unnecessary to rule on CTP's March 14, 2016 motion to extend deadlines.

stricken and that a default judgment be issued. On March 24, 2016, CTP filed its pre-hearing exchange. On April 4, 2016, this case was transferred to me. Respondent's pre-hearing exchange was due on April 11, 2016 as ordered by Judge Kessel on February 19, 2016. Respondent has submitted nothing to date.

II. Striking Respondent's Answer

Respondent has failed to comply with the Acknowledgment and Pre-Hearing Order that required a timely response to discovery requests, has failed to comply with the Order compelling discovery responses to be provided by March 9, 2016, and has failed to meet the April 11, 2016 Pre-hearing exchange deadline as ordered by the Acknowledgement and Pre-Hearing Order. Respondent did not comply with any of CTP's discovery requests. In addition, Respondent did not respond to CTP's Motion to Compel Discovery, despite being given the opportunity to do so. Additionally, Respondent failed to file its Pre-hearing exchange by the April 11, 2016 deadline. Respondent's failure to effectively prosecute and defend actions taken over the course of the proceedings have interfered with the orderly and speedy processing of this case, further warranting imposition of sanctions. *See* 21 C.F.R. § 17.35(a) (1)(2) and (3).

Due to Respondent's failure to comply with three separate judicial orders as described above, 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(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 to be egregious, warranting striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b). Respondent did not comply with any of the three orders, nor did it provide any adequate justification for not doing so.

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 9:55 a.m. on November 29, 2014, at Respondent's business establishment, 100 North Courtland Street, Chamberlain, South Dakota 57325, an FDA-commissioned inspector observed Respondent's staff selling a package of

Marlboro cigarettes to a person younger than 18 years of age;

- In a warning letter dated December 30, 2014, CTP informed Respondent of the inspector's November 29, 2014 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) . The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action;
- At approximately 8:04 p.m. on April 23, 2015, at Respondent's business establishment, 100 North Courtland Street, Chamberlain, South Dakota 57325, FDA-commissioned inspectors documented Respondent's staff selling a package of Marlboro Gold Pack 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.

These facts establish Respondent Bottle Shop'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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), 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.

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent Albert S. Fox d/b/a Bottle Shop. 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/
Catherine Ravinski
Administrative Law Judge