

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-2782)

Complainant,

v.

In Chul Lee and Hye Jung Lee
d/b/a Parks Place / Shell,

Respondent.

Docket No. C-15-3585

Decision No. CR4582

Date: April 13, 2016

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, In Chul Lee and Hye Jung Lee d/b/a Parks Place / Shell, located at 608 West Yelm Avenue, Yelm, Washington 98597¹, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Parks Place / Shell 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 Parks Place / Shell. During the hearing process, Respondent

¹ On December 17, 2015, CTP's Motion for Leave to Amend its complaint to correct Respondent's address was granted. The original complaint listed Respondent's address as 608 Yelm Avenue, Yelm, Washington 98597.

has failed to comply with two judicial directions regarding CTP's discovery request. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

CTP began this matter on August 21, 2015 by serving an administrative complaint seeking a \$500 civil money penalty on Respondent Parks Place / Shell, at 608 West Yelm Avenue, Yelm, Washington 98597. Respondent timely filed an answer to CTP's complaint on September 18, 2015. Administrative Law Judge Steven T. Kessel 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 December 16, 2015. On January 22, 2016, 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 February 18, 2016 letter issued under the direction of Judge Kessel, Respondent was given until March 4, 2016, to object to CTP's motion. On February 18, 2016, Judge Kessel also issued an Order that extended the parties' pre-hearing exchange deadlines.

On March 8, 2016, CTP filed an updated status report requesting that its Motion to Compel Discovery be granted and that deadlines applicable to CTP be extended. The updated status report stated that Respondent had not objected to CTP's Motion to Compel discovery or produced any documents responsive to CTP's request for production of documents.

On March 14, 2016, Judge Kessel issued an order granting CTP's Motion to Compel Discovery and extending the pre-hearing exchange deadlines. The Order allowed Respondent until March 30, 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 April 4, 2016, this case was reassigned to me. On April 4, 2016, CTP filed a motion to extend deadlines.² On April 4, 2016, CTP also filed a Status Report and a Motion to Impose Sanctions advising that Respondent had not complied with Judge Kessel's March 14, 2016 Order. In its Motion to Impose Sanctions, CTP asked that Respondent's answer be stricken and that a default judgment be issued.

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, and Respondent has failed to comply with the Order compelling discovery responses to be provided by March 30, 2016. 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. 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 the Acknowledgment and Pre-Hearing Order, and Respondent's failure to comply with the Order compelling discovery responses, 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 sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b). Respondent did not comply with the order 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:

² As I am issuing a default decision, it is unnecessary to rule on CTP's April 4, 2016 motion to extend deadlines.

- At approximately 10:59 a.m. on April 4, 2014, at Respondent's business establishment, 608 West Yelm Avenue, Yelm, Washington 98597, an FDA-commissioned inspector observed Respondent's staff selling a package of Camel 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 letter³ dated May 29, 2014, CTP informed Respondent of the inspector's April 4, 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 1:31 p.m. on April 25, 2015, at Respondent's business establishment, 608 West Yelm Avenue, Yelm, Washington 98597, FDA-commissioned inspectors documented Respondent's staff selling a package of Camel Crush Regular Fresh 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 Parks Place / Shell'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.

³ In the warning letter, Respondent was Shell / Food Mart.

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent In Chul Lee and Hye Jung Lee d/b/a Parks Place / Shell. 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