

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-3894)

Complainant

v.

Derya Corp.  
d/b/a Sunniland Country Store,

Respondent.

Docket No. T-17-4993

Decision No. TB2779

Date: June 5, 2018

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an Administrative Complaint on Respondent, Derya Corp. d/b/a Sunniland Country Store, located at 13213 County Road 858, Immokalee, Florida 34142, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Sunniland Country Store impermissibly sold cigarettes or 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 \$5,591 civil money penalty against Respondent Sunniland Country Store. During the hearing process, Respondent failed to comply with judicial orders, which constitutes misconduct that has interfered with the speedy, orderly, or fair conduct of this proceeding, and failed to defend this action by not appearing for a hearing. I, therefore, strike Respondent's Answer and issue this decision of default judgment.

## I. Procedural History

CTP began this matter on June 30, 2017, by serving an Administrative Complaint, seeking a \$5,591 civil money penalty, on Respondent, Derya Corp. d/b/a Sunniland Country Store, at 13213 County Road 858, Immokalee, Florida 34142. *See* Compl., DAB E-File Docket (Dkt.) No. 1; Proof of Service, Dkt. No. 1b. Respondent, through counsel, timely filed its Answer to CTP's Complaint on July 12, 2017. Answer, Dkt. No. 3. I issued an Acknowledgement and Pre-Hearing Order on July 17, 2017, that set deadlines for the parties' submissions including the discovery deadlines.

On August 16, 2017, CTP, with Respondent's authorization, filed a Joint Status Report. Joint Status Report, Dkt. No. 6. On August 28, 2017, CTP filed a Motion for Protective Order claiming Respondent's Request for Production of Documents (RFP) served on CTP on August 16, 2017 seeks privileged and exempt from public disclosure documents. Mot. for Protective Order, Dkt. No. 7. An August 30, 2017 letter issued by my direction allowed Respondent until September 8, 2017, to file any response to CTP's Motion for Protective Order. Aug. 30, 2017 By Direction Letter (BDL), Dkt. No. 8, at 2. On September 7, 2017, Respondent filed a Response to CTP's Motion for Protective Order. Resp't's Response, Dkt. No. 9. On September 18, 2017, I issued an Order granting in part and denying in part CTP's Motion for Protective Order, allowing: (1) CTP until October 3, 2017 to produce documents responsive to Respondent's RFP that have not been subject to a protective order and submit any privilege log; (2) Respondent until October 18, 2017 to file any challenge to any document on CTP's privilege log; (3) CTP until November 8, 2017 to file its prehearing exchange; and (4) Respondent until November 29, 2017 to file its prehearing exchange. Sept. 18, 2017 Order, Dkt. No. 10.

On September 21, 2017, Respondent moved to amend its Answer to add additional defenses stating that CTP had no objection to the amendment. Resp't's Mot. to Amend Answer, Dkt. No. 11. On September 22, 2017, I granted Respondent leave to amend its Answer. Sept. 22, 2017 Order, Dkt. No. 12. On October 3, 2017, Respondent filed its Amended Answer and Defenses. Am. Answer & Defenses, Dkt. No. 13. On the same day, CTP filed its Privileged Document Log. Privilege Doc. Log, Dkt. No. 14.

CTP timely filed its pre-hearing exchange on November 8, 2017. CTP's pre-hearing exchange included an Informal Brief of Complainant (Dkt. No. 15), a list of proposed witnesses and exhibits (Dkt. No. 15a), and 14 numbered exhibits (CTP Exs. 1-14, Dkt. Nos. 15b-15o). On November 28, 2017, Respondent timely filed its pre-hearing exchange, which included an Informal Brief of Respondent (Dkt. No. 16) and two exhibits (Resp't's Exs. 1-2, Dkt. Nos. 16a-16b). Respondent also moved to abate the hearing and decision in this matter pending final ruling by the United State Court of Appeals for the District of Columbia Circuit in *Orton Motor Inc. v. U.S. Dep't of Health & Human Servs.*, and indicated that CTP opposed the motion. Resp't's Mot. to Abate, Dkt. No. 16c. A November 29, 2017 letter issued by my direction allowed CTP until

December 13, 2017 to respond to Respondent's motion. Nov. 29, 2017 BDL, Dkt. No. 17. On December 13, 2017, CTP timely filed its Opposition to Respondent's Motion to Abate. CTP's Opp'n, Dkt. Nos. 18-18c. I denied Respondent's Motion to Abate on December 15, 2017, and scheduled a telephone pre-hearing conference for January 11, 2018. Dec. 15, 2017 Order, Dkt. No. 19.

On January 11, 2018, I held a pre-hearing conference in this case. During the pre-hearing conference, the parties communicated their intent to cross-examine each others' witnesses. *See* Jan. 12, 2018 Order, Dkt. No. 22, at 1. Respondent asked to amend its Answer and pre-hearing exchange, including its informal brief and exhibits, and CTP objected. *Id.* I allowed Respondent until January 29, 2018 to file a motion demonstrating good cause for amending the Answer and the pre-hearing exchange and presenting any proposed additional arguments and exhibits. *Id.* at 1-2.

On January 30, 2018, I issued an Order scheduling a telephone hearing for March 29, 2018, at 1:00 PM Eastern Time. Jan. 30, 2018 Order, Dkt. No. 23. Shortly after, Respondent filed a Motion for Reconsideration of Order Scheduling Telephone Hearing claiming an unsuccessful attempt to file its motion to amend answer and informal brief on the January 29, 2018 deadline, and requesting to reschedule the telephone hearing scheduled for March 29, 2018. Resp't's Mot. for Reconsideration, Dkt. No. 24. I granted Respondent's motion on January 30, 2018, allowing Respondent until February 1, 2018 to re-file its motion to amend. Jan. 30, 2018 Order, Dkt. No. 25, at 1-2. CTP was allowed until February 14, 2018, to respond to Respondent's motion to amend. *Id.* at 2. By a separate Order, I cancelled the March 29, 2018 hearing. Jan. 30, 2018 Order, Dkt. No. 26.

On January 30, 2018, Respondent filed a Motion to Amend Answer to Administrative Complaint and the Informal Brief of Respondent, and submitted a proposed amended answer and informal brief. Dkt. Nos. 27-27a. On February 14, 2018, CTP filed its opposition to Respondent's Motion to Amend. Dkt. Nos. 29-29e. On February 15, 2018, I issued an Order denying Respondent's motion ordering the parties to confer before February 23, 2018 with respect to the dates that the parties are available for a telephone hearing. Feb. 15, 2018 Order, Dkt. No. 30, at 2.

On February 22, 2018, based on the parties' proposed hearing dates (Dkt. No. 31), I issued an Order Scheduling In-Person Telephone Hearing for April 19, 2018, at 1:00 PM Eastern Time. Feb. 22, 2018 Order, Dkt. No. 32, at 1. The parties were provided with a call-in telephone number and passcode. *Id.* at 2. The February 22, 2018 Order was served on Respondent's counsel via the Departmental Appeals Board Electronic Case Filing (E-File) system. *Id.* at 3.

On March 27, 2018, Respondent's counsel filed a Motion to Withdraw as Counsel for Respondent due to irreconcilable differences. Mot. to Withdraw as Counsel for Resp't,

Dkt. No. 33. The Motion to Withdraw provided Respondent's last known address as 13213 County Road 858, Immokalee, Florida 34142, the same address that appears in the Complaint (Dkt. No. 1 ¶ 7) and on the Proof of Service (Dkt. No. 1b). Respondent's counsel served Respondent at its mailing address of record and at Respondent's e-mail address. Dkt. No. 33, at 2.

On March 28, 2018, I issued an Order granting counsel's Motion to Withdraw and reminded Respondent about the hearing scheduled for April 19, 2018, at 1:00 PM Eastern Time. Mar. 28, 2018 Order, Dkt. No. 34, at 2. The March 28, 2018 Order again provided parties with a call-in telephone number and passcode for the telephone hearing. *Id.* at 2. The Order directed Respondent to register for E-File by no later than April 6, 2018. *Id.* The Order also established a deadline of April 12, 2018 to file evidentiary objections. *Id.* The March 28, 2018 Order was sent to Respondent's mail and e-mail addresses of record. Dkt. Nos. 34-35a.

On April 12, 2018, CTP filed its Objection to Evidence arguing Respondent's Exhibit 2 entitled "Employee Letter" (Dkt. No. 16b) should be excluded from evidence as it was a testimony of three signatories of the letter not submitted under penalty of perjury. CTP's Obj. to Evid., Dkt. No. 36. Respondent filed no evidentiary objections.

Respondent and its witness, Paula Miguel, failed to appear at the April 19, 2018 hearing call. Apr. 19, 2018 Order, Dkt. No. 37, at 2. On April 19, 2018, I issued an Order to Show Cause allowing Respondent until April 30, 2018 to show cause for its failure to appear at the April 19, 2018 hearing. *Id.* at 2. Respondent was warned that failure to respond to the Order to Show Cause may result in sanctions. *Id.* Also in the Order, I sustained CTP's objection to Respondent's Exhibit 2 and did not admit Respondent's Exhibit 2 into evidence. *Id.* at 1. The Order admitted Respondent's Exhibit 1 and CTP's Exhibits 1 through 14 into evidence. *Id.* The April 19, 2018 Order was sent to Respondent's mailing address of record. *Id.* at 3.

On May 2, 2018, the United States Postal Service returned Respondent's copy of the March 28, 2018 Order with a sticker stating "Return to Sender Attempted – Not Known Unable to Forward" and a handwritten note stating "RETURN NO MORE." Returned Mail, Dkt. No. 39.

On May 7, 2018, although there was no evidence the address was improper, I issued an Order extending Respondent's deadline to respond to my Order to Show Cause from April 30, 2018 to May 9, 2018. Dkt. No. 40, at 1. I again warned Respondent that failure to respond to the Order may result in sanctions and enclosed a copy of my April 19, 2018 Order to Show Cause. Dkt. Nos. 40-40a. The May 7, 2018 Order along with the April 19, 2018 Order to Show Cause were e-mailed to Respondent's e-mail address of record. Dkt. Nos. 41-41b.

On May 22, 2018, Respondent's copy of the April 19, 2018 Order was returned with a sticker stating "Return to Sender Undeliverable as Addressed Unable to Forward" and a handwritten note stating "NO MORE." Returned Mail, Dkt. No. 42.

As of the date of this Decision, no response from Respondent has been received.

## **II. Striking Respondent's Answer**

Pursuant to 21 C.F.R. § 17.35(a), I may sanction a party for:

- (1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;
- (2) Failing to prosecute or defend an action; or
- (3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

Indeed, "[i]f a party fails to prosecute or defend an action . . . after service of a notice of hearing, the presiding officer may dismiss the action or may issue an initial decision imposing penalties and assessments." 21 C.F.R. § 17.35(e).

Here, Respondent failed to comply with multiple judicial orders. 21 C.F.R. § 17.35(a)(1). Specifically, Respondent failed to comply with my February 22, 2018 Order Scheduling In-Person Telephone Hearing, as clarified in my March 28, 2018 Order, by failing to appear at the April 19, 2018 hearing as scheduled. Respondent also failed to comply with my March 28, 2018 Order, by not registering for E-File by the April 6, 2018 deadline. Respondent further failed to comply with my April 19, 2018 Order to Show Cause, as extended by my May 7, 2018 Order, by never showing cause for its failure to appear at the hearing by the May 9, 2018 deadline. Respondent has not filed any notice advising that his mailing or e-mail address of record has changed. Respondent's failure to comply with my orders constitutes misconduct that has interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a)(1), (a)(3).

In addition, Respondent's failure to appear at the April 19, 2018 telephonic hearing after service of the February 22, 2018 order scheduling a hearing and the March 28, 2018 reminder, constitutes failure to defend this action. 21 C.F.R. § 17.35(a)(2), (e). Respondent's failure to defend this action is further demonstrated by Respondent's failure to take any action with regard to this case after the withdrawal of its counsel, which contrasts with its active participation, through counsel, prior to the withdrawal. Indeed, Respondent has not participated in the defense of this action in any meaningful fashion after the withdrawal of counsel. Because of the passage of time with no action on the part of Respondent, I find that sanctions are appropriate under 21 C.F.R. § 17.35.

The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure. 21 C.F.R. § 17.35(b). I find and conclude that Respondent's misconduct, failure to comply with my orders, and failure to defend this action are sufficiently egregious to warrant striking the Answer and issuing a decision without further proceedings.

### III. Default Decision

Striking Respondent's Answer leaves the Complaint unanswered. I am, therefore, 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. 21 C.F.R. § 17.11. Specifically:

- On January 4, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-1400, FDA Docket Number FDA-2016-H-4569, against Respondent for three<sup>1</sup> violations of 21 C.F.R. pt. 1140 within a 24-month period. Compl., Dkt. No. 1 ¶ 11. CTP alleged those violations to have occurred at Respondent's business establishment, 13213 County Road 858, Immokalee, Florida 34142, on October 7, 2014, March 10, 2015, and June 20, 2016. *Id.* ¶¶ 7, 11.
- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and agreed to pay a monetary penalty in settlement of that claim. *Id.* ¶ 12. Further, "Respondent expressly waived its right to contest such violations in subsequent actions." *Id.*
- At approximately 4:55 p.m. on May 20, 2017, at Respondent's business establishment, 13213 County Road 858, Immokalee, Florida 34142, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age. *Id.* ¶ 9. 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. *Id.*

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<sup>1</sup> Two violations were documented on October 7, 2014, one violation on March 10, 2015, and one on June 20, 2016. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

These facts establish Respondent Sunniland Country Store'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 also* 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 also* 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),<sup>2</sup> 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 are younger than 18 years of age.

A \$5,591 civil money penalty is permissible under 21 C.F.R. § 17.2.

### Order

For these reasons, I enter default judgment in the amount of \$5,591 against Respondent, Derya Corp. d/b/a Sunniland Country Store. 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.

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/s/  
Wallace Hubbard  
Administrative Law Judge

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<sup>2</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.