Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-R-6625)

Complainant

v.

Landover Services, Inc.
d/b/a US Fuel,

Respondent.

Docket No. T-18-490

Decision No. TB2942

Date: July 30, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (complaint) against Respondent, Landover Services, Inc. d/b/a US Fuel, which alleges that US Fuel sold cigarettes and/or smokeless tobacco to minors, 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. The complaint likewise alleges that Respondent US Fuel committed five repeated violations of FDA tobacco regulations within a 36-month period, and therefore, CTP seeks to impose a No-Tobacco-Sale Order against Respondent US Fuel for a period of 30 consecutive calendar days.

Although Respondent filed an answer to the complaint, it has subsequently failed to comply with judicial orders, failed to defend its action, and engaged in conduct which has interfered with the speedy, orderly, and fair conduct of this proceeding. I therefore **STRIKE** Respondent's answer and issue this decision of default judgment.

I. Introduction

CTP began this case by serving a complaint on Respondent US Fuel at 6705 Martin Luther King Jr. Highway, Hyattsville, Maryland 20785, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Respondent's staff impermissibly sold cigarettes and/or smokeless tobacco to minors and failed to verify that tobacco product purchasers were of sufficient age, and it seeks a No-Tobacco-Sale Order against Respondent for a period of 30 consecutive calendar days.

On December 12, 2017, Respondent filed a timely Answer to the complaint via the DAB E-File system. I issued an Acknowledgment and Pre-Hearing Order (APHO) on December 21, 2017, which explained to the parties what they must do to present evidence and arguments in this case. The APHO also established deadlines for discovery requests and pre-hearing briefs. The APHO directed CTP to file its pre-hearing exchange by March 13, 2018, and it directed Respondent to file its pre-hearing exchange by April 3, 2018.

On January 19, 2018, CTP filed a status report which indicated that the parties were engaged in settlement discussions and intended to continue those conversations. On March 6, 2018, CTP filed a Motion to Compel Discovery and a Motion to Extend Deadlines in the APHO. On March 7, 2018, I granted the Motion to Extend Deadlines in the APHO. Also on that date, the staff attorney assigned to this case issued a letter by my direction allowing Respondent until March 21, 2018, to file a response to CTP's Motion to Compel Discovery. Respondent did not file a response to CTP's Motion to Compel Discovery or otherwise respond to the March 7, 2018 letter. Accordingly, I granted the Motion to Compel Discovery on March 22, 2018. Respondent was given until April 6, 2018, to comply with CTP's Request for Production of Documents. My March 22, 2018 Order also extended the parties respective pre-hearing exchange deadlines.

In accordance with the March 22, 2018 Order, CTP timely filed its pre-hearing exchange and a list of exhibits on April 27, 2018. Respondent did not file a pre-hearing exchange or any supporting exhibits by its May 18, 2018 deadline. On May 25, 2018, I issued a Pre-Hearing Order scheduling a pre-hearing conference on Monday, July 9, 2018, at 11:00 AM Eastern Time, so that the parties could discuss the issues remaining in the case in light of Respondent's failure to file a pre-hearing exchange, proposed exhibits, or witness testimony.

The pre-hearing conference was convened as scheduled on July 9, 2018, and Mr. Michael Varrone and Ms. Rachel Babbitt appeared on behalf of CTP. Neither Respondent nor Respondent's counsel appeared for the call, nor did they contact the Departmental Appeals Board (DAB) prior to the call to indicate they would be unable to attend. On July 10, 2018, I issued an Order to Show Cause, allowing Respondent until July 16, 2018,

to show cause for its failure to appear at the pre-hearing conference. On July 16, 2018, Respondent's counsel filed a response to my order stating that counsel "overestimated [his] abilities and assumed that [he] would be present in [his] office and available after arriving home from summer vacation with [his] family," on the afternoon of July 9, 2018. In support of his response, counsel submitted a flight itinerary booked on June 9, 2018, showing that he departed Tampa, Florida at 10:25 AM on July 9, 2018, scheduled to arrive in Baltimore, Maryland, at 12:45 PM the same afternoon.

II. Striking Respondent's Answer

Pursuant to 21 C.F.R. § 17.35(a)(1), (2), and (3),[1] I am striking Respondent's answer for failing to comply with judicial orders, failing to defend the case, and interfering with the speedy, orderly, and fair conduct of the hearing. Specifically, Respondent did not comply with CTP's Request for Production of Documents until after I granted CTP's Motion to Compel Discovery. Counsel also failed to appear for the July 9, 2018 pre-hearing conference. Moreover, in his response to my Order to Show Cause, counsel did not demonstrate that extraordinary circumstances prevented him from appearing for the conference.

An extraordinary circumstance is defined as a circumstance which is beyond a party's ability to control that prevents the party from discharging the duty to file a timely response. *4447 Corner Store*, DAB CR1037 (2012). Ordinary negligence, simple neglect, and/or attorney error do not amount to an extraordinary circumstance. *Neves v. Holder*, 613 F.3d 30, 36 (1st Cir. 2010); *Cmty Dental Servs. v. Tani*, *282 F.3d 1164*, 1168–69 (9th Cir. 2002); *In re Aquatic Dev. Grp., Inc.*, 352 F.3d 671, 679 (2nd Cir. 2003). Counsel's failure to appear due to "overestimat[ing] [his] abilities and assum[ing] [he] would be present in [his] office," does not constitute an extraordinary circumstance, because inadvertently booking a flight at the same time as a pre-hearing conference is within counsel's control. Counsel did not offer any explanation as to why he booked a flight to Baltimore, Maryland, when he was already scheduled to appear at a pre-hearing conference on the same day at the same time. The Pre-Hearing Order scheduling the July 9, 2018 conference was issued on May 25, 2018, more than six weeks prior to the conference and two weeks before counsel booked his flight. Counsel had several weeks to predict the conflict and avoid it by rescheduling the conference or the date and time of his return from vacation, but he failed to do so.

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[1] 21 C.F.R. § 17.35 governs the issuance of sanctions. That section reads, in relevant part, "(a) The presiding officer may sanction a person, including any party or counsel 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."

Even assuming, *arguendo*, that extraordinary circumstances had arisen on the day of the conference, counsel made no attempt to contact the DAB on July 9, 2018, to indicate that he was unavailable due to unforeseen circumstances. After I issued an Order to Show Cause on July 10, 2018, Respondent waited until July 16, 2018, the due date of the response, to file a response providing a reason for his absence. Counsel's explanation for failing to attend the pre-hearing conference does not demonstrate extraordinary circumstances. Therefore, sanctions are appropriate in this case.

The issue is whether striking Respondent's answer and issuing a default judgment is appropriate under these circumstances. The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply. I find that Respondent's failure to comply with CTP's discovery request until after an Order Compelling Discovery was issued interfered with the speedy and orderly conduct of this proceeding. 21 C.F.R. § 17.35(a)(1), (a)(3). In addition, counsel's failure to appear at the July 9, 2018 pre-hearing conference after service of the May 25, 2018 Order constitutes failure to defend the action. 21 C.F.R. § 17.35(a)(2). Counsel's conduct is 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, CTP alleges the following facts in its complaint:

- On February 20, 2014, CTP initiated the first civil money penalty action, CRD Docket Number C-14-1760, FDA Docket Number FDA-2014-H-1238, against Respondent for violations[2] of 21 C.F.R. pt. 1140. CTP alleged those violations to have occurred at Respondent's business establishment, 6705 Martin Luther King

[2] Respondent's original violation for selling cigarettes and/or smokeless tobacco to a minor occurred on October 8, 2013.

Jr. Highway, Landover, Maryland 20785,[3] on October 8, 2013, and February 20, 2014;[4]

- The first action concluded when Respondent admitted the allegations contained in the complaint issued by CTP and paid the agreed upon penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";

- On March 10, 2015, CTP initiated the second civil money penalty action, CRD Docket Number C-15-1537, FDA Docket Number FDA-2015-H-0709, against Respondent for violations[5] of 21 C.F.R. pt. 1140. CTP alleged those violations to have occurred at Respondent's business establishment, 6705 Martin Luther King Jr. Highway, Hyattsville, Maryland 20785, on October 17, 2014;

- The second action concluded when Respondent admitted the allegations contained in the complaint issued by CTP and paid the agreed upon penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";

- On October 30, 2015, CTP initiated the third civil money penalty action, CRD Docket Number T-17-377, FDA Docket Number FDA-2015-H-3859, against Respondent for six violations of 21 C.F.R. pt. 1140 within a 48-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 6705 Martin Luther King Jr. Highway, Hyattsville, Maryland 20785, on June 23, 2015;

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[3] I note that Respondent's address in the first CMP action was listed as "6705 Martin Luther King Jr. Highway, Landover, Maryland 20785," and its address in the subsequent actions was listed as "6705 Martin Luther King Jr. Highway, Hyattsville, Maryland 20785." Respondent has made no indication that its store location has changed or that it is not the same Respondent from the original complaint.

[4] According to CTP's chart entitled "Violative Inspection Dates," the original violations of 21 C.F.R. Part 1140 for selling cigarettes and/or smokeless tobacco occurred on October 8, 2013. Although Respondent also sold cigarettes and/or smokeless tobacco to a minor on February 20, 2014, this date was not counted as a repeated violation, as it occurred outside of the 36 month window during which Respondent committed five repeated violations. *See* complaint ¶ 1, Figure 1 entitled "Violative Inspection Dates."

[5] Respondent's original violation for failure to 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 occurred on October 17, 2014.

- The third action concluded when an Initial Decision was entered by an Administrative Law Judge, "finding Respondent liable for the June 23, 2015 violations and concluding that the Respondent committed six violations in a forty-eight month period as set forth in the complaint";

- At approximately 12:34 p.m. on June 21, 2017, at Respondent's business establishment, 6705 Martin Luther King Jr. Highway, Hyattsville, Maryland 20785, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box 100s cigarettes 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.

These facts establish that Respondent is liable 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. § 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, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1)[6], no retailer may sell tobacco products 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 tobacco product purchasers are younger than 18 years of age.

Taking the above-alleged facts as true, Respondent had five repeated violations of regulations found at 21 C.F.R. pt. 1140. Respondent violated the prohibition against selling cigarettes and/or smokeless tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on October 8, 2013, and repeated those violations on October 17, 2014, June 23, 2015, and June 21, 2017. On October 17, 2014, Respondent also violated the requirement that retailers verify, by means of photographic identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i), and repeated those violations on June 23, 2015, and June 21, 2017. Therefore, Respondent's actions constitute violation of law, which merit a No-Tobacco-Sale Order.

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for five repeated violations of the regulations found at 21 C.F.R. pt. 1140. The maximum period of time for the first No-Tobacco-Sale Order received by a retailer is 30 consecutive calendar days. *See* Pub. L. 111–31, div. A, title I, § 103(q)(1)(A), June 22, 2009, 123 Stat. 1838,

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

1839; Food & Drug Admin., Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers at 5-6, *available at* http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM252955.pdf (last updated Dec. 15, 2016); Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with Order at 3-4, *available* at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf (last updated August 2015).

Order

For these reasons, I enter default judgment against Respondent Landover Services, Inc. d/b/a US Fuel, in the form of a No-Tobacco-Sale Order, for a period of 30 consecutive calendar days. During this period of time, Respondent shall stop selling cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products regulated under the Federal Food, Drug, and Cosmetic Act. 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/
Wallace Hubbard
Administrative Law Judge