

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-R-5759)

Complainant,

v.

Joe Eideh  
d/b/a 7-Eleven 34428,

Respondent.

Docket No. T-17-6603

Decision No. TB2782

Date: June 5, 2018

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Joe Eideh d/b/a 7-Eleven 34428, alleging facts and legal authority sufficient to justify imposition of a No-Tobacco-Sale Order against Respondent for a period of 30 consecutive calendar days. Respondent answered the Complaint, but has failed to comply with multiple judicial orders and directions during the administrative proceedings. 21 C.F.R. § 17.35(a)(1). Accordingly, pursuant to 21 C.F.R. § 17.35(c)(3), I strike Respondent's Answer, issue this decision of default judgment, and impose a No-Tobacco-Sale Order against Respondent for a period of 30 consecutive calendar days.

**I. Procedural History**

CTP initiated this case by serving a Complaint on Respondent on September 21, 2017. Proof of Service, DAB E-File Docket (Dkt.) No. 1b. The Complaint alleges that Respondent's staff impermissibly sold cigarettes or smokeless tobacco to minors and failed to verify that the purchasers were of sufficient age, thereby violating the Federal

Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. Compl., Dkt. No. 1 ¶¶ 6, 9-10. CTP seeks a No-Tobacco-Sale Order against Respondent for a period of 30 consecutive calendar days. *Id.* ¶ 14.

In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should file an answer or request an extension of time within which to file an answer. *Id.* ¶ 12; Cover Letter, Dkt. No. 1a, at 1. On October 20, 2017, Respondent attempted to submit an answer to CTP's Complaint via the DAB E-File system, but the uploaded answer form was blank. Answer, Dkt. No. 3. On October 25, 2017, two days after the answer deadline, Respondent filed a completed Answer form (Answer) opposing the No-Tobacco-Sale Order and submitted a letter claiming technical difficulties that led to the untimely filing of the Answer. *See* Dkt. Nos. 4, 5.

On November 1, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO). APHO, Dkt. No. 6. In the APHO, I found that Respondent made a good faith attempt to file timely Answer and, therefore, found good cause to accept the Answer despite the late filing. *Id.* at 1. I directed the parties to file a joint status report and explained to the parties what they must do to present evidence and arguments in this case. *Id.* at 3-7. I also explained that the parties may request copies of documents relevant to this case and that the requesting party must serve the request for documents no later than December 11, 2017. *Id.* at 7. I further explained that "a party receiving such a request must provide the requested documents no later than 30 days after the request has been made." *Id.* *See also* 21 C.F.R. § 17.23(a).

On December 1, 2017, consistent with my APHO and with Respondent's authorization, CTP filed a joint status report indicating the parties were unable to reach a settlement and intended to proceed to a hearing. Joint Status Report, Dkt. No. 7. The status report further stated that the first CMP action resulted in Respondent paying in full the agreed upon civil money penalty amount, while the second CMP action resulted in a judgment against Respondent for \$5,000 with no payment received. *Id.* at 1.

As part of the discovery process, CTP served a Request for Production of Documents (RFP) on Respondent on December 6, 2017. Dkt. Nos. 8a-8c. Although the APHO allowed a party 10 days from receipt of a RFP to move for a protective order, no such motion was filed by Respondent. *See* APHO, Dkt. No. 6, at 7-8.

On January 10, 2018, pursuant to 21 C.F.R. § 17.32(a), CTP filed an Unopposed Motion to Extend Deadlines stating that Respondent contacted CTP on January 3, 2018, requesting additional time to respond to CTP's RFP. Unopposed Mot. to Extend Deadlines, Dkt. No. 8, at 1. The Motion further indicated that CTP consented to extending Respondent's response deadline to January 29, 2018. *Id.* at 2. The parties also requested to extend pre-hearing exchange deadlines to allow parties to properly prepare

their pre-hearing exchanges. *Id.* On January 11, 2018, I issued an Order allowing Respondent until January 29, 2018 to respond to CTP's RFP and extending the parties' respective pre-hearing exchange deadlines. Jan. 11, 2018 Order, Dkt. No. 9.

On February 8, 2018, pursuant to 21 C.F.R. § 17.32(a), CTP filed a Motion to Compel Discovery indicating that CTP received no response to its RFP. Mot. to Compel, Dkt. No. 11. On the same day, CTP also filed a Motion to Extend Deadlines, requesting a 30-day extension of time of CTP's pre-hearing exchange to allow Respondent to comply with CTP's RFP and provide CTP with sufficient time to prepare its pre-hearing exchange. Mot. to Extend Deadlines, Dkt. No. 10. Notably, Respondent never filed a motion for a protective order. A February 9, 2018 letter issued by my direction allowed Respondent until February 26, 2018 to file a response to CTP's Motion to Compel Discovery. Feb. 9, 2018 By Direction Letter (BDL), Dkt. No. 12; *see also* 21 C.F.R. § 17.32(c). On February 9, 2018, I also issued an Order extending the parties' respective pre-hearing exchange deadlines. Feb. 9, 2018 Order, Dkt. No. 13.

Respondent failed to respond to CTP's Motion to Compel Discovery. Accordingly, on February 27, 2018, I issued an Order granting CTP's Motion to Compel Discovery and ordering Respondent to comply with CTP's RFP by March 15, 2018. Feb. 27, 2018 Order, Dkt. No. 14. I warned Respondent that “[f]ailure 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 . . . .”<sup>1</sup> *Id.* at 1-2.

On March 21, 2018, CTP filed a Motion to Impose Sanctions advising that Respondent failed to comply with my February 27, 2018 Order. Mot. to Impose Sanctions, Dkt. No. 15. CTP sought sanctions against Respondent in the form of striking the Respondent's Answer and issuance of a default judgment in this case. *Id.* at 3. On March 21, 2018, CTP also filed a Motion to Extend Deadlines. Mot. to Extend Deadlines, Dkt. No. 15a. In a March 21, 2018 letter issued by my direction, Respondent was given until April 5, 2018, to file a response to CTP's Motion to Impose Sanctions. Mar. 21, 2018 BDL, Dkt. No. 16; *see also* 21 C.F.R. § 17.32(c). On March 21, 2018, I also issued an Order staying all pre-hearing deadlines pending resolution of the Motion to Impose Sanctions. Mar. 21, 2018 Order, Dkt. No. 17.

On April 3, 2018, Respondent filed a letter response indicating documents requested by CTP were mailed to CTP in early January 2018. Letter, Dkt. No. 18. Respondent, however, provided no evidence showing the documents were actually mailed to or received by CTP. The letter also stated that Respondent was out of the country from January 25, 2018 until the first week of March with no email access. *Id.* Again,

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<sup>1</sup> I note that the February 27, 2018 Order inadvertently referenced imposition of “a civil money penalty.” It should have correctly referenced imposition of “a no-sale-tobacco order.” *See* Feb. 27, 2018 Order, Dkt. No. 14, at 2.

Respondent provided no evidence confirming he was out of the country or had no email access. The letter further stated that upon his return in the first week of March, Respondent discovered that a deadline to file a response to CTP's Motion to Impose Sanctions was April 5, 2018. *Id.* Respondent failed to provide any explanation for being unable to comply with my February 27, 2018 Order directing Respondent to comply with CTP's RFP by March 15, 2018. Although Respondent's letter stated that, upon his return in early March, Respondent called CTP's office and was told the documents he sent were not received, Respondent failed to provide any evidence that the documents responsive to CTP's RFP were ever resubmitted to CTP. *Id.*

In an April 5, 2018 letter issued by my direction, CTP was given until April 10, 2018 to file any response to Respondent's April 3, 2018 letter. Apr. 5, 2018 BDL, Dkt. No. 19. On April 10, 2018, CTP filed a Response stating that, prior to filing its Motion to Impose Sanctions, CTP checked multiple offices to verify that CTP received no response from Respondent. CTP's Response, Dkt. No. 20, at 1. In its Response, CTP further indicated that upon receipt of Respondent's April 3, 2018 letter, CTP checked once again with multiple offices to confirm no documents responsive to CTP's RFP were received from Respondent. *Id.* at 2.

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

Pursuant to 21 C.F.R. § 17.35(a)(1), I may sanction a party for failing to comply with an order, subpoena, rule, or procedure governing the proceeding. As outlined above, Respondent repeatedly failed to comply with my Orders. Although the APHO discovery response deadlines were extended twice, Respondent failed to comply with any of the established deadlines. Respondent failed to respond to CTP's RFP in violation of my January 11, 2018 Order. Respondent also failed to comply with my February 27, 2018 Order Granting CTP's Motion to Compel Discovery, requiring Respondent to comply with document production by March 15, 2018. Further, Respondent did not avail itself of the opportunity to respond to CTP's motion to compel pursuant to the letter issued at my direction on February 9, 2018.

Although Respondent submitted a response to CTP's Motion to Impose Sanctions, the response included no evidence in support of the stated reasons for being unable to comply with judicial orders. Furthermore, Respondent's unsubstantiated claim that documents responsive to CTP's RFP were mailed (although never received by CTP) casts considerable doubt on the veracity of his assertions in general. Indeed, Respondent made no attempt to resubmit documents responsive to CTP's RFP between the first week of March and present. Accordingly, I find that Respondent failed to comply with my Orders and has not established good cause for failure to comply with my Orders. The conduct of Respondent in connection with the proceedings in this case since the Answer was filed warrants sanctions. 21 C.F.R. §§ 17.35(a)(1), 17.35(c)(3). I, therefore, grant CTP's Motion to Impose Sanctions. 21 C.F.R. § 17.35(a)(1).

The harshness of the sanctions I impose must relate to the nature and severity of the misconduct or failure to comply. 21 C.F.R. § 17.35(b). I find Respondent's repeated failure to comply, despite multiple warnings, is sufficiently egregious to warrant striking the Answer and issue a decision by default, without further proceedings. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

Accordingly, due to Respondent's noncompliance, I am striking Respondent's Answer and issuing this Initial Decision and Default Judgment. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

### **III. Default Decision**

Striking Respondent's Answer leaves the Complaint unanswered. Therefore, I am required to "assume the facts alleged in the [C]omplaint to be true" and, if those facts establish liability under the Act, issue a default judgment and impose a No-Tobacco-Sale-Order. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- On December 1, 2014, CTP initiated the first civil money penalty action, CRD Docket Number C-15-482, FDA Docket Number FDA-2014-H-2008, against Respondent for three<sup>2</sup> violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 73 Storey Avenue, Newburyport, Massachusetts 01950, on August 14, 2013 and June 11, 2014;
- The first action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions;"
- On July 15, 2015, CTP initiated the second civil money penalty action, CRD Docket Number C-15-3153, FDA Docket Number FDA-2015-H-2239, against

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<sup>2</sup> In the first civil money action, two violations were documented on August 14, 2013, and two on June 11, 2014. When determining the number of violations for a civil money penalty, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations, in accordance with customary practice. However, when determining the number of violations for a No-Tobacco-Sale Order, CTP counted both of the August 14, 2013 violations (sale to a minor and failure to verify identification) as Respondent's original violations.

Respondent for five violations of 21 C.F.R. pt. 1140 within a 36-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 73 Storey Avenue, Newburyport, Massachusetts 01950, on March 11, 2015;

- The second action concluded when Respondent admitted to all of the allegations in the Complaint and an Initial Decision was entered by the administrative law judge, finding Respondent liable for all violations and imposing a \$5,000 penalty;
- At approximately 4:58 PM on June 8, 2017, at Respondent's business establishment, 73 Storey Avenue, Newburyport, Massachusetts 01950, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box 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 United States 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, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1),<sup>3</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.

Taking the above-alleged facts as true, Respondent had six repeated violations of regulations found at 21 C.F.R. pt. 1140, within a 36-month period. Respondent violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on August 14, 2013, and repeated those violations on June 11, 2014, March 11, 2015, and June 8, 2017. Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i), on August 14, 2013, and repeated those violations on June 11, 2014, March 11, 2015, and June 8, 2017. Therefore, Respondent's actions constitute violations of law that merit a No-Tobacco-Sale Order.

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<sup>3</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for six repeated violations of the regulations found at 21 C.F.R. pt. 1140. *See* FDA Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers: Guidance for Industry, at 3, 5-6 (Dec. 2016),

<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM252955.pdf>. The maximum period of time for the first No-Tobacco-Sale Order received by a retailer is 30 calendar days. *See* FDA Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order: Guidance for Tobacco Retailers, at 4 (Aug. 2015),

<http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

### **ORDER**

For these reasons, I enter default judgment against Respondent, Joe Eideh d/b/a 7-Eleven 34428, 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.

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/s/  
Wallace Hubbard  
Administrative Law Judge