

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,
(FDA No. FDA-2017-H-3321)

Complainant

v.

Shih Noble
d/b/a 7 Eleven Store 32409A,

Respondent.

Docket No. T-17-4467

Decision No. TB2464

Date: February 22, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Shih Noble d/b/a 7 Eleven Store 32409A, located at 2980 South Highway A1A, Melbourne Beach, Florida 32951, for five violations of 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, within a thirty-six month period. Specifically, CTP alleges that 7 Eleven Store 32409A violated the Act by impermissibly selling cigarettes and smokeless tobacco to minors, and failing to verify, by means of photographic identification containing a date of birth, that the purchasers were 18 years of age or older.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$5,591 civil money penalty on Respondent 7 Eleven Store 32409A, at 2980 South Highway A1A, Melbourne Beach, Florida 32951, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. After being properly served with CTP's Complaint in this matter, Respondent filed a timely Answer on July 3, 2017. The answer was submitted by Respondent's counsel, who had filed a

Notice of Appearance three days earlier, on June 30, 2017. I issued an Acknowledgment and Pre-hearing Order (APHO) on July 6, 2017. I 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 August 14, 2017. The APHO also established a deadline of September 25, 2017 for all pre-hearing exchanges from CTP to Respondent, and a deadline of October 16, 2017 for all pre-hearing exchanges from Respondent to CTP. I warned the parties that failure to comply with my orders, including the APHO, could subject them to sanctions. APHO ¶ 16, *citing* 21 C.F.R. § 17.35.

On September 21, 2017, CTP filed a Motion to Extend Deadlines. In its Motion, CTP indicated that Respondent is located in Melbourne Beach, Florida, and counsel for Respondent is located in St. Petersburg, Florida, both areas that were affected by Hurricane Irma. CTP also indicated that it could not file the Motion as unopposed because they were unable to reach Respondent's counsel. Accordingly, on September 22, 2017, I issued an Order granting the Motion, extending the parties' pre-hearing deadlines.

On October 13, 2017, CTP filed an Unopposed Motion to Extend Deadlines and Notice of Pending Settlement. The October 13, 2017 Motion indicated that the parties had reached an agreement to settle the matter and requested that I extend the deadlines for the parties' pre-hearing exchanges. On October 16, 2017, I issued an Order granting the Motion, again extending the parties' pre-hearing deadlines.

CTP filed its pre-hearing exchange on November 22, 2017. CTP's pre-hearing exchange included an Informal Brief of Complainant, a list of proposed witnesses and exhibits, and fifteen (15) numbered exhibits. CTP's exhibits included the declarations of two witnesses. Respondent did not file a pre-hearing exchange or offer any witnesses.

On December 28, 2017, I held a telephonic pre-hearing conference in this case. Both parties were present on the call. I explained to the parties that the sole purpose of an administrative hearing under the applicable regulations is to afford the parties an opportunity for cross-examination of exchange witnesses.¹ Respondent indicated that it would like to cross-examine one of CTP's witnesses, Mr. Castiello, the FDA designated inspector for the State of Florida who conducted the disputed inspection at Respondent's place of business on February 27, 2017 in this matter. Subsequently, on December 29, 2017, I issued an order scheduling a telephone hearing in this matter for January 22, 2018 at 11:00 a.m.

On January 22, 2018, at 12:50 a.m., Respondent's counsel submitted an email stating that he had a family medical emergency and would be unable to attend the hearing that

¹ Respondent's counsel also indicated that he was unsure what happened to the settlement agreement that the parties had executed prior to CTP's October 13, 2017 Notice of Pending Settlement.

morning. Respondent's counsel did not submit a formal Motion to Continue, nor did he provide evidence of the family medical emergency. On that same date, at 11:00 a.m., Respondent failed to appear.

On February 2, 2018, I issued an Order requiring Respondent to show cause for its failure to appear at the January 22, 2018 hearing. In my February 2, 2018 Order, I required Respondent's counsel to "provide a detailed explanation for his non-appearance at the hearing and provide documentation of the family medical emergency." I warned counsel that failure to show good cause may result in sanctions, including the issuance of an Initial Decision finding Respondent liable for the violations listed in the Compliant and imposing a civil money penalty. On February 9, 2018, Respondent submitted a Response to Order to Show Cause. In the response, Respondent's counsel generally described the alleged family emergency, but did not submit any documentation as was specifically required by my February 2, 2018 Order.

Decision on the Record

Pursuant to 21 C.F.R. § 17.35(e), if a party fails to defend an action after service of a notice of hearing, I may impose sanctions and issue an initial decision imposing penalties and assessments. Here, Respondent was served with notice regarding the January 22, 2018 hearing by order dated December 29, 2017. *See* 21 C.F.R. § 17.35(e).

Despite that notice, Respondent failed to appear at the scheduled hearing. In addition, Respondent did not file a hearing exchange or any other documentation since it filed its July 6, 2017 Answer. At the pre-hearing conference held on December 12, 2017, Respondent's counsel stated that he was not representing Respondent at the time a settlement agreement was reached with CTP and thus was not sure why payment of the agreed-upon penalty was not made.

The documentation of record establishes that counsel filed an entry of appearance in this case on June 30, 2017, and filed the answer on Respondent's behalf on July 3, 2017. The APHO was sent to counsel on July 6, 2017, as was CTP's status report dated October 13, 2017 regarding the settlement agreement reached by the parties. These documents belie counsel's assertion that he did not represent Respondent at the time settlement discussions occurred, and the joint status report was issued. In fact, the record clearly shows that counsel had already been the sole representative for Respondent for more than three months when these events transpired, and that he actively participated in the settlement process. He, and he alone, is fully accountable for all actions taken or not taken in this case since he filed a Notice of Appearance on June 30, 2017 and answer on July 3, 2017. 21 C.F.R. § 17.35(a)(3).

Although Respondent's counsel submitted a Response to the Order to Show Cause, the response did not include documentation as required by my February 22, 2018 Order.

Counsel's failure to produce the required documentation in support of his stated reasons for being unable to appear at the scheduled hearing reflects a repeated inability to comply with judicial orders, and a failure to defend this action. Furthermore, his previous attempt to disclaim any knowledge of or participation in the earlier settlement discussions in the face of documentary evidence to the contrary, casts considerable doubt on the veracity of his assertions in general. Accordingly, I find that Respondent has not established good cause for failure to appear at the January 22, 2018 hearing. 21 C.F.R. § 17.35(a)(2), (e). The conduct of Respondent's counsel in connection with the proceedings in this case since the Answer was filed warrants severe sanctions. 21 C.F.R. § 17.35(a)(2), (a)(3), (e). I find that Respondent has lost the right to a hearing to cross-examine CTP's witness as he chose to do at the pre-hearing conference. 21 C.F.R. § 17.35(b). Therefore, I will decide this case on the basis of the written record. 21 C.F.R. § 17.35(e).

Analysis

I. Violations

In its Complaint, CTP alleges that Respondent 7 Eleven Store 32409A committed five violations of the Act and its implementing regulations within a thirty-six month period. CTP makes the following allegations:

- On December 13, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-1135, FDA Docket Number FDA-2016-H-4256, against Respondent for three² violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred at Respondent's business establishment, 2980 South Highway A1A, Melbourne Beach, Florida 32951, on February 28, 2016 and May 27, 2016;
- 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. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";
- At approximately 7:47 p.m. on February 27, 2017, at Respondent's business establishment, 2980 South Highway A1A, Melbourne Beach, Florida 32951, an

² Two violations were documented on February 28, 2016 (sale of a tobacco product to a minor and failure to verify identification), and two on May 27, 2016 (sale of smokeless tobacco to a minor and failure to verify identification). 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.

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.

Complaint; Informal Brief of Complainant. CTP supports its allegations with a number of evidentiary exhibits; of particular relevance is the written declaration of the FDA-commissioned inspector who conducted the February 27, 2017 inspection. CTP Ex. 8; *see* CTP Exs. 9, 10, 12; 21 C.F.R. § 17.33(b).

In its Answer, Respondent 7 Eleven Store 32409A denied CTP's allegations. Respondent did not provide any evidence to refute CTP's allegations, nor did Respondent provide any evidence to support any defenses.

In order to prevail, Complainant must prove Respondent's liability by a preponderance of the evidence. *See* 21 C.F.R. § 17.33(b). As such, I as the factfinder must assess whether, on the whole, I am convinced that the greater weight of the evidence supports Complainant's account. *See Sec'y of Labor v. Keystone Coal Min. Corp.*, 151 F.3d 1096, 1103 (D.C. Cir. 1998). Since Respondent provided no evidence to refute any of the allegations, I have only Respondent's Answer to consider. Respondent's Answer denied the allegations in paragraphs 9, 10, 11, and 12 of the Complaint. The Answer did not contain any evidence or explanation as to why the allegations were denied.

Therefore, I find that the facts as set forth in the Complaint establish Respondent 7 Eleven Store 32409A'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); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1),³ 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 purchasers are younger than 18 years of age.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent 7 Eleven Store 32409A is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations

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

at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the maximum penalty amount, \$5,591, against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint ¶ 1. In its Answer, Respondent did not specify if it believed the civil money penalty CTP requested is too high.

When determining the amount of a civil money penalty, I am required to take into account “the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.” 21 U.S.C. § 303(f)(5)(B).

i. Nature, Circumstances, Extent and Gravity of the Violations

Respondent 7 Eleven Store 32409A has failed to comply with the Act and its implementing regulations on three separate occasions, on February 28, 2016, May 27, 2016, and February 27, 2017. I found that Respondent committed a violation of selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and a violation for failing to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i). I also found that Respondent had admitted to three previous violations of the Act and its implementing regulations. Thus, Respondent has been charged by CTP with five violations in accordance with its customary practice to charge only one violation for the initial inspection, even though the applicable regulations would permit charging for more than one. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

ii. Respondent’s Ability to Pay

CTP is seeking a \$5,591 civil money penalty against Respondent 7 Eleven Store 32409A. Respondent has not provided any argument or evidence that it lacks the ability to pay the \$5,591 civil money penalty.

iii. Effect on Ability to do Business

CTP is seeking a \$5,591 civil money penalty against Respondent 7 Eleven Store 32409A. Respondent has not provided any argument or evidence that such a penalty will affect its ability to do business.

iv. History of Prior Violations

Respondent Shih Noble d/b/a 7 Eleven Store 32409A is a repeated violator of FDA’s tobacco regulations prohibiting the sale of tobacco products to minors. Respondent has

been the subject of a prior civil money penalty action. *See* CRD Docket Number T-17-1135, FDA Docket Number FDA-2016-H-4256. This is the second civil money penalty action brought against Respondent within the past thirty-six months for violations of the Act and its implementing regulations, bringing the total number of violations to five. *See* Complaint ¶¶ 1, 11-12. Specifically, Respondent's violation count includes three sales to a minor in violation of 21 C.F.R. § 1140.14(a)(1), and three failures to verify identification in violation of 21 C.F.R. § 1140.14(a)(2)(i).

v. Degree of Culpability

I have concluded that Respondent is liable for five violations of the Act and its implementing regulations within thirty-six months. I hold Respondent fully culpable for each of those violations.

vi. Additional Mitigating Factors

Mitigation is an affirmative defense for which Respondent bears the burden of proof. 21 C.F.R. § 17.33(c). Respondent has provided no evidence in support of mitigation.

vii. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$5,591 to be reasonable and appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

Conclusion

For the foregoing reasons, I enter judgment in the amount of \$5,591 against Respondent Shih Noble d/b/a 7 Eleven Store 32409A. 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