

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2016-H-0720)

Complainant

v.

DHS Energy Sales, LLC  
d/b/a 7-Eleven,

Respondent.

Docket No. T-16-416

Decision No. TB2327

Date: January 9, 2018

**INITIAL DECISION**

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, DHS Energy Sales, LLC d/b/a 7-Eleven, located at 7401 East Broadway Avenue, Tampa, Florida 33619, for three 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 twenty-four month period. Specifically, CTP alleges that 7-Eleven violated the Act by impermissibly selling cigarettes to minors, and failing to verify, by means of photo 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 \$500 civil money penalty on Respondent 7-Eleven, at 7401 East Broadway Avenue, Tampa, Florida 33619, 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 June 17, 2016. Respondent's former counsel also filed a Notice of Appearance at that time. I issued an Acknowledgment and Prehearing Order (APHO) on July 7, 2016. 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 8, 2016. On August 8, 2016, Respondent sent CTP a request for the production of documents.

In response to Respondent's discovery request, CTP filed a Motion for a Protective Order on August 18, 2016. On August 29, 2016, Respondent filed a response to CTP's Motion for a Protective Order. Further, on September 8, 2016, Respondent filed a "Motion to Compel Better Responses to First Request for Production and for Sanctions." CTP, in turn, filed its own Motion to Compel Discovery on September 19, 2016, and filed a response to Respondent's motion on September 26, 2016. Respondent filed a response to CTP's Motion to Compel Discovery on October 4, 2016.

On November 28, 2016, I issued an Order granting in part and denying in part CTP's August 18, 2016 Motion for a Protective Order. My Order also denied Respondent's "Motion to Compel Better Responses to First Request for Production and for Sanctions" and granted CTP's Motion to Compel Discovery. The Order set forth, among other things, that CTP must submit all documents to Respondent not subject to the protective order no later than December 28, 2016; that CTP must file any privilege logs by December 28, 2016; that Respondent had until January 12, 2017 to challenge any document included in CTP's privilege log; and that the prehearing exchange deadlines were to be extended.

On December 28, 2016, CTP filed its privilege log. On January 12, 2017, Respondent filed a Motion to Compel documents listed in CTP's privilege log, and CTP filed its response on January 27, 2017. On February 3, 2017, CTP filed a motion to extend the prehearing exchange deadlines pending resolution of the parties' ongoing discovery dispute. I issued an order on February 6, 2017, granting that motion and extending the deadlines. On February 17, 2017, CTP filed a Second Motion to Compel. On February 23, 2017, I issued an Order again extending the parties' prehearing deadlines. On February 27, 2017, CTP withdrew its Second Motion to Compel.

On April 6, 2017, CTP filed another Motion to Extend Deadlines so that discovery issues could be resolved. I granted that motion on April 12, 2017 and ordered that the prehearing deadlines be extended.

On April 18, 2017, I issued a Protective Order for the documents set forth in CTP's privilege log. My Order also extended CTP's prehearing exchange deadline to May 22, 2017 and Respondent's prehearing exchange deadline to June 12, 2017.

CTP filed its prehearing exchange on May 22, 2017. CTP's pre-hearing exchange included an Informal Brief of Complainant, a list of proposed witnesses and exhibits, and thirty-eight (38) numbered exhibits. CTP's exhibits included the declarations of two witnesses. On June 1, 2017, Respondent's counsel submitted a Notice of Appearance, noting the substitution of two attorneys from the same firm. Respondent filed its prehearing exchange on June 12, 2017. Respondent's prehearing exchange included an Informal Brief of Respondent, a list of proposed witnesses and exhibits, and two (2) numbered exhibits. Respondent's exhibits included the declaration of one witness. Respondent's exchange also included a request that this case be dismissed and that the declaration of one of CTP's witnesses, Laurie J. Sternberg be stricken because the declaration was unsigned. On July 10, 2017, I issued an Order finding no cause for dismissal and directed CTP to file a response to Respondent's objection to Ms. Sternberg's declaration by July 31, 2017. Additionally, the Order scheduled a pre-hearing conference for August 8, 2017 at 10:00 a.m. to resolve any outstanding issues. On July 28, 2017, CTP filed its response to the Respondent's request to strike Ms. Sternberg's declaration.

On August 8, 2017, I held a telephonic prehearing conference in this case. 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. Respondent indicated that it would like to cross-examine one of CTP's witnesses, Mr. Pulliam, the inspector in this matter. CTP declined to cross-examine Respondent's sole witness. Consequently, on August 8, 2017, I issued an order scheduling a telephone hearing in this matter for September 13, 2017 at 1:00 p.m. Due to Hurricane Irma, which affected the area where Respondent's business is located, on September 8, 2017, I postponed the scheduled hearing and requested that the parties inform me by September 29, 2017 of their availability for future hearing dates.

On September 26, 2017, counsel for Respondent filed a Notice of Withdrawal, stating that Respondent had retained alternate counsel. On September 29, 2017, attorney Donald Anderson notified the Departmental Appeals Board by e-mail that he had been retained by Respondent. After receiving available dates from both counsel for CTP and counsel for Respondent, on October 10, 2017, I issued an order scheduling a telephone hearing for November 16, 2017. The order also directed Respondent's counsel to register with the Departmental Appeals Board's Electronic Filing System (DAB E-File) by October 20, 2017. Further, Respondent's counsel was given until October 27, 2017 to indicate which of CTP's exchange witnesses he wished to cross-examine at the November 16, 2017 hearing. That order was e-mailed directly to Respondent's counsel.

On November 2, 2017, I issued an additional order indicating that the deadlines set forth in my October 10, 2017 had passed and that, to date, Respondent's counsel had not registered for the DAB E-File nor had he indicated which of CTP's witnesses he wished to cross-examine at the hearing. My order stated that the hearing would continue as

scheduled on November 16, 2017. That order was also e-mailed directly to Respondent's counsel.

Despite being ordered twice to register for and utilize the DAB E-File, on November 10, 2017, six days before the scheduled hearing, Respondent's counsel submitted a Motion to Continue by e-mail. Respondent's counsel's motion stated that an "unexpected medical issue" would prevent attendance at the scheduled hearing. Respondent's counsel also added that he had "just recently been provided with voluminous discovery" to review. Despite no documentation being provided attesting to a medical emergency, by order dated November 14, 2017, I granted the Motion to Continue and rescheduled the hearing for December 5, 2017 at 1:00 p.m. The order indicated if either party was unable to appear on December 5, 2017 at 1:00 p.m., that the parties could agree to an alternate hearing date and inform me by November 22, 2017. The order again directed Respondent's counsel to register with the DAB E-File by November 20, 2017 and to submit the names of the witnesses he wished to cross-examine by November 27, 2017. Again, the order was e-mailed directly to Respondent's counsel.

Respondent's counsel failed to register for the DAB E-File or submit the names of the witnesses that he wished to cross-examine by the date set in the November 14, 2017 Order. Furthermore, the parties did not notify me that they could not attend the scheduled hearing. On the date and time of the scheduled hearing, December 5, 2017 at 1:00 p.m., both Respondent and Respondent's counsel failed to appear.

On December 11, 2017, six days after the scheduled hearing, Respondent filed a Motion for Rehearing and Reconsideration stating that an "inadvertent scheduling error" caused him to be absent from the hearing, and that Respondent should not be penalized for his error.

### **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 December 5, 2017 hearing by order dated November 14, 2017. Despite that notice, neither Respondent nor Respondent's counsel appeared at the scheduled hearing. I note that Respondent, in his December 11, 2017 Motion, tacitly concedes he received notice given his excuse for non-appearance was an "inadvertent scheduling error."

In addition to failing to appear at the hearing that it requested, Respondent failed to respond to three separate orders each of which directed Respondent's newly-retained counsel to (1) register for the DAB E-File and (2) identify any witnesses he sought to cross-examine at the hearing. Thus, the reasons stated in support of Respondent's

Motion for Rehearing and Reconsideration are simply not credible as Respondent's failure to properly defend its case began long before the hearing that it failed to attend.

Respondent's refusal to minimally participate in a proceeding that it requested in its Answer, coupled with its flagrant non-compliance with my orders, warrant severe sanctions. I find that Respondent has lost the right to a hearing to cross-examine CTP's witnesses. Therefore, I will decide this case on the basis of the written record. *See* 21 C.F.R. § 17.35(e).

## **Analysis**

### **I. Violations**

In its Complaint, CTP alleges that Respondent 7-Eleven committed four violations of the Act and its implementing regulations within a twenty-four month period, but only charged Respondent with one (1) violation for the first inspection, and a total of three (3) violations, in accordance with its customary practice. CTP makes the following allegations:

- At approximately 5:50 p.m. on December 10, 2014, at Respondent's business establishment, 7401 East Broadway Avenue, Tampa, Florida 33619, an FDA commissioned inspector documented Respondent's staff selling a package of Marlboro Special Blend 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;
- In a warning letter dated January 15, 2015, CTP informed Respondent of the inspector's December 10, 2014 documented violations, and that such actions violate federal law. 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 5:32 p.m. on November 12, 2015, at Respondent's business establishment, 7401 East Broadway Avenue, Tampa, Florida 33619, an FDA commissioned inspector documented Respondent's staff selling a package of 305's Menthol Kings 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 officer who participated in both inspections.

In both its Answer and its Informal Brief, Respondent 7-Eleven denies all of CTP's allegations. The thrust of Respondent's argument is that Respondent did not employ individuals matching the descriptions reflected in the December 10, 2014 or the November 12, 2015 inspection reports. Specifically, Respondent argues that it never employed a female employee with blonde hair and glasses as alleged in the December 10, 2014 inspection report and that it never employed an employee named "Shelly" with light brown hair and glasses as alleged in the November 12, 2015 inspection report. Informal Brief of Respondent at 4-5.

Respondent provides the written declaration of the Respondent's business owner as evidence to support this argument. Resp. Ex. 1. In addition, Respondent points to its payroll register to support that it did not employ anyone with the name "Shelly" on the date of the November 12, 2015 inspection. Informal Brief of Respondent at 5; CTP Ex. 33.

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 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). Respondent's argument largely focuses on its allegation that the Inspector's descriptions of its store employees are inaccurate. According to Respondent, the Inspector's descriptive inaccuracies should cast doubt upon whether or not the violations in question actually occurred. However, Respondent has raised no other issue and provided no other evidence to show that the violations did not occur. Indeed, the possibility exists that the descriptions provided in evidence by CTP are not wholly accurate. However, Respondent chose not avail itself of the opportunity to cross-examine the Inspector at a hearing in order to attempt to impeach his sworn written testimony. The Inspector was made available and ready to testify at the hearing, at considerable expenditure of time and effort by Complainant. Furthermore, Respondent's reliance on the contents of its payroll registers is misplaced and unpersuasive. The payroll report does not include physical descriptions of employees, nor does it account for an employee that may go by a diminutive or augmentative form of their "formal" name. Accordingly, based upon the entirety of the record in this case, I am convinced that the greater weight of the evidence supports Complainant's allegations.

Therefore, I find that these facts establish Respondent 7-Eleven'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)<sup>1</sup>, no retailer may sell cigarettes 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 purchasers are younger than 18 years of age.

## **II. Civil Money Penalty**

Pursuant to 21 U.S.C. § 333(f)(9), Respondent 7-Eleven is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the maximum penalty amount, \$500, against Respondent for three violations of the Act and its implementing regulations within a twenty-four month period. Complaint ¶ 1. In its Informal Brief, CTP continues to assert that a \$500 civil money penalty is appropriate. Informal Brief of Complainant at 14.

Respondent 7-Eleven asserts that it is a franchisee of 7-Eleven, Inc. and that "7-Eleven franchise agreements contain an 'obey all laws' provision that subjects [Respondent] to termination of its rights to operate the franchise if it is found to have violated the law." Respondent asserts that a finding of a violation "may constitute a breach of the franchise agreement, which would jeopardize its contractual right to continue its business" and that Respondent "takes violations of this nature very seriously, which is why [Respondent] has procedures in place to avoid such violations, including its point of sale system and training." Informal Brief of Respondent at 7.

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 has failed to comply with the Act and its implementing regulations on two separate occasions, in December 2014 and November 2015. I have found that Respondent committed two violations of selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and two violations 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). Respondent has been charged by Complainant with three of those violations in accordance with its customary

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<sup>1</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

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 \$500 civil money penalty against Respondent 7-Eleven. Respondent has not provided any argument or evidence that it lacks the ability to pay the \$500 civil money penalty. To the contrary, Respondent's business owner signed a declaration under penalties of perjury stating that he had "the ability to pay the \$500 fine that [CTP] seeks" in this case. CTP Ex. 38.

**iii. Effect on Ability to do Business**

Respondent claims that "a finding here of 21 C.F.R. 1140.14...may constitute" a breach of its franchise contract with 7-Eleven. Informal Brief of Respondent at 7; *see also* Resp. Ex. 3. This, however, is a contractual matter between Respondent and 7-Eleven and does not weigh upon my decision. Respondent, as a party to that agreement, should have kept that provision in mind prior to allowing repeated violations to occur. Additionally, it is unclear whether Respondent could continue to operate as a business regardless of its status as a 7-Eleven franchise. Based on the available evidence, I cannot conclude that a \$500 civil monetary penalty would severely hinder Respondent's ability to continue lawful retail operations.

**iv. History of Prior Violations**

While the current action is the first civil money penalty action that CTP has brought against Respondent, CTP issued a warning letter to Respondent informing it of the inspector's December 10, 2014 documented violations. Complaint ¶ 11. That letter warned that Respondent's failure to correct its violations might result in a civil money penalty or other regulatory action. *Id.* Despite that warning letter, however, Respondent was found to have committed the exact same violations during an inspection only 11 months later in November 2015.

**v. Degree of Culpability**

I have concluded that Respondent is liable for three violations of selling tobacco products to minors, and hold Respondent fully culpable for each of those violations of the Act and its implementing regulations.

**vi. Additional Mitigating Factors**

In his declaration, Respondent's business owner stated that he requires all employees of Respondent to complete a course regarding restrictions for tobacco sales and watch an FDA video entitled "Compliance Training for Tobacco Retailers." R. Ex. 1 at 2. However, Respondent did not provide any evidence that these internal requirements were in place prior to 2015 when the most recent the violations occurred.

**vii. Penalty**

Based on the foregoing reasoning, I find a penalty amount of \$500 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 \$500 against Respondent DHS Energy Sales, LLC d/b/a 7-Eleven. 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/

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Catherine Ravinski  
Administrative Law Judge