

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-3146)

Complainant

v.

STD Enterprise Inc.  
d/b/a 7-Eleven 33850,

Respondent.

Docket No. T-17-4305

Decision No. TB2754

Date: May 25, 2018

**INITIAL DECISION**

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, STD Enterprise Inc. d/b/a 7-Eleven 33850, located at 621 West State Street, Geneva, Illinois 60134, 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 33850 violated the Act by impermissibly selling cigarettes and smokeless tobacco 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 \$5,591 civil money penalty on Respondent 7-Eleven 33850, at 621 West State Street, Geneva, Illinois 60134, and by filing a copy of the complaint with the Food and

Drug Administration's (FDA) Division of Dockets Management. Respondent requested an extension of time to answer CTP's complaint, I granted that request, and subsequently issued a default judgment in this case because Respondent failed to file an answer. I later found that extraordinary circumstances excused Respondent from filing a timely answer, and reopened the case. Respondent then filed an answer to CTP's complaint in which Respondent admitted that it committed the current violation of selling cigarettes to a minor, and requested a reduced civil money penalty and that the current violation be dismissed from the Respondent's record. On December 7, 2017, I issued an Acknowledgement and Prehearing Order that set deadlines for the parties to file their pre-hearing exchanges. CTP filed its pre-hearing exchange on February 27, 2018 that consisted of a brief and 17 exhibits (CTP Exs. 1-17). Respondent 7-Eleven 33850 subsequently filed its pre-hearing exchange, which consisted of a brief and a number of photographs. In its brief, Respondent admitted to the current allegation in the Complaint and requested a reduced civil money penalty.

### **Decision on the Record**

In its pre-hearing exchange, CTP submitted two witness declarations. Respondent 7-Eleven 33850 has not submitted direct testimony. I held a pre-hearing conference on April 16, 2017, during which Respondent informed me that it did not intend to cross-examine CTP's witnesses. Because Respondent 7-Eleven 33850 has not submitted any direct testimony, there is no one for CTP to request to cross-examine. Therefore, I will decide this case based on the written record.

I allowed both parties to submit final briefs on the issue of the penalty amount. On April 27, 2018, Respondent timely filed its brief requesting that a fine of \$1,000 or less be imposed, and submitted a March 2018 financial summary with its brief. On April 30, 2018, CTP timely filed its brief requesting that I impose a civil money penalty of \$5,591, which is the full amount requested. CTP's brief also argued against admitting the Respondent's March 2018 financial summary into evidence as it was not timely exchanged pursuant to 21 C.F.R. § 17.25(a), and further noted that I had informed Respondent during the pre-hearing conference that the time for submitting evidence had passed. I will not admit Respondent's March 2018 financial summary into the record or consider it in my decision. Respondent did not timely submit this evidence and failed to provide cause for the untimely submission.

I admit into evidence the CTP's exhibits identified as CTP Ex. 1 – CTP Ex. 17, and the exhibits that Respondent attached to its informal brief that consist of photographs.

## Analysis

### I. Violations

In its Complaint, CTP alleges that Respondent 7-Eleven 33850 committed five violations of the Act and its implementing regulations within a thirty-six month period. On December 5, 2017, 7-Eleven 33850 filed an answer to the Complaint requesting a reduced civil money penalty and dismissal of the current violation. Answer. Additionally, on March 21, 2017, 7-Eleven 33850 filed an informal brief, in which it admitted to the current allegation in the Complaint, and requested a reduction of the civil money penalty. Informal Brief of Respondent.

Respondent does not contest any of CTP's allegations. CTP asserts the following:

- CTP initiated its first civil money penalty action, CRD Docket Number C-15-3786, FDA Docket Number FDA-2015-H-3001, with a September 1, 2015 Complaint filed against Respondent 7-Eleven 33850 for two violations of 21 C.F.R. pt. 1140 within a 12-month period. CTP alleged those violations to have occurred on December 11, 2014, and May 12, 2015;
- The first civil money penalty 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;
- On September 7, 2016, CTP initiated a second civil money penalty action, CRD Docket Number T-16-1541, FDA Docket Number FDA-2016-H-2320, against Respondent 7-Eleven 33850 for four violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred on December 11, 2014, May 12, 2015, and January 25, 2016;
- That second action concluded when an Administrative Law Judge entered an Initial Decision and Default Judgment that found that the violations in the second civil money penalty action occurred;
- During a subsequent inspection, at approximately 11:41 a.m. on February 20, 2017, at Respondent's business establishment, 621 West State Street, Geneva, Illinois 60134, 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.

CTP asserts that these allegations, and accompanying evidence, establish a basis for liability against Respondent. Respondent 7-Eleven 33850 has not disputed these allegations.

Therefore, I find that these facts establish Respondent STD Enterprise Inc. d/b/a 7-Eleven 33850'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). Under 21 C.F.R. § 1140.14(a)(1)<sup>1</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.

## II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent 7-Eleven 33850 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, \$5,591, against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint ¶ 1. In its Informal Brief and Final Brief, CTP continues to assert that a \$5,591 civil money penalty is appropriate. Informal Brief of Complainant at 9; Final Brief of Complainant at 3.

Respondent 7-Eleven 33850 argues that its profits are declining, its costs are rising and that there is a high turnover of employees. Final Brief of Respondent at 1. Respondent asks for a fine of \$1,000 or less to be imposed. *Id.* at 2. Respondent asserts that it is "doing everything that I can reasonably do to be in compliance" that it has "learned so much." *Id.*

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).

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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>.

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

Time and again, Respondent 7-Eleven 33850 has failed to comply with the Act and its implementing regulations. Respondent admitted to two violations for selling cigarettes and smokeless tobacco to persons younger than 18 years of age. And, later an Initial Decision and Default Judgment was entered finding that Respondent committed four violations of the Act. Specifically, the Initial Decision and Default Judgment found three violations for selling cigarettes and smokeless tobacco to persons younger than 18 years of age, and one 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. Now, Respondent again admits to selling cigarettes to persons younger than 18 years of age. 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 33850. Respondent 7-Eleven 33850 asserts that the "income generated from my store is at a negative for the last two months. I am facing declining sales and declining customer counts." Informal Brief of Respondent at 4. As pointed out in CTP's brief, Respondent provided no documentation evidencing its statements. Informal Brief of Complainant at 10.

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

There is nothing in the evidentiary record that shows the effect a civil money penalty will have on Respondent 7-Eleven 33850's ability to do business. CTP asserts that "[a] \$5,591 civil money penalty will not affect respondent's ability to do business. Respondent may continue to sell tobacco products and other products at the establishment." Informal Brief of Complainant at 10. Respondent requests that its fine be reduced to \$1,000 or less and states that "[a]nything greater could ruin me. I don't want to lose my business." Though Respondent asserts that a civil money penalty of \$5,591 will have a substantial effect on Respondent's ability to do business, the record does not include evidence to show the effects of a civil money penalty of this amount on Respondent's ability to do business.

**iv. History of Prior Violations**

The current action is the third civil money penalty action brought against Respondent 7-Eleven 33850 in less than three years for violations of the Act and

its implementing regulations. In the first civil money penalty action, CRD Docket Number C-15-3786, FDA Docket Number FDA-2015-H-3001, Respondent violated the prohibition against selling cigarettes and smokeless tobacco to persons younger than 18 years of age on December 11, 2014, and May 12, 2015. Respondent settled these claims with CTP for an undisclosed penalty amount.

In the second civil money penalty action, CRD Docket Number T-16-1541, FDA Docket Number FDA-2016-H-2320, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, on January 25, 2016. And, on that same date, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.

Including the current action before me, Respondent's total violation count is four sales to a minor, in violation of 21 C.F.R. § 1140.14(a)(1), and one failure to verify the identification of persons who were not over the age of 26, in violation of 21 C.F.R. § 1140.14(a)(2)(i). I agree with CTP that the repeated "violations show an . . . inability to sell tobacco products in accordance with federal tobacco regulations." Informal Brief of Complainant at 10. While Respondent has already paid a civil money penalty for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

**v. Degree of Culpability**

Over the course of three civil money penalty actions, Respondent 7-Eleven 33850 admitted to three of the violations set forth in the current action, and an Initial Decision and Default Judgment was entered against Respondent that included the two violations that Respondent did not admit to. I hold Respondent 7-Eleven 33850 fully culpable for all five violations of the Act and its implementing regulations.

**vi. Additional Mitigating Factors**

Respondent 7-Eleven 33850 states that it has taken additional steps to prevent future violations. Specifically, Respondent states that it has taken the following actions:

1. I have a zero-tolerance policy. If an age restricted product is being purchased in my store my clerks must ask for an ID if the person looks under the age of 30. If they don't, the clerk is terminated for not following company policy.
2. That ID must be scanned into our POS. 7-Eleven has a new POS age restricted screen that pops up and an ID must be scanned into the

system. If the picture matches the person and the age is legal the POS will allow the sale to continue. If the ID is expired or the birthdate is too young, the ID scan will alert the clerk to refuse the sale. (There is a problem that I brought to 7-Eleven's attention that if a student produces a fake ID the ID will still scan because the information on the scan strip must have the legal age birthdate.) I would look into this.

3. All Employees must watch the training video from 7- Eleven called coming of age.
4. BARRS will continue to come into our business once per month to see if we are carding guest for age restricted products.
5. I have employed employees to run my own compliance checks on our employees.
6. I have clear signage on my counters, doors and displays saying WE CARD. I also have a calendar present for customers to see what their birthday must be at the minimum to purchase age restricted products. This was supplied by the CTP.

Informal Brief of Respondent at 3.

Further, in Respondent's final brief on the amount of the penalty, it stressed how much it has learned during this process, and stated that it "would be more than willing to help others see the importance of having proper policies in place." Final Brief of Respondent at 2-3. Further, Respondent again reiterated that if its employees "choose not to use the resources and training that I have equipped them with, then they will no longer be a part of my team going forward." *Id.* at 2.

#### **vii. Penalty**

I acknowledge the numerous steps taken by Respondent to ensure additional future violations do not occur. Respondent has clearly taken these violations very seriously, accepted responsibility for the violations and taken great measures to ensure that they are not repeated. Further, these additional measures clearly required additional cost, as well as Respondent's time, to implement. Based on the foregoing reasoning, I find a reduced penalty amount of \$2,000 to be appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

**Conclusion**

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$2,000 against Respondent, STD Enterprise Inc. d/b/a 7-Eleven 33850, 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.

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/s/

Catherine Ravinski  
Administrative Law Judge