

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-5716)

Complainant

v.

W.B.P. Enterprises, Inc.  
d/b/a Holden's Party Store,

Respondent.

Docket No. T-17-6576

Decision No. TB2783

Date: June 6, 2018

**INITIAL DECISION**

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) against Respondent, W.B.P. Enterprises, Inc. d/b/a Holden's Party Store, located at 2055 South Milford Road, Milford, Michigan 48381, for six 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 48-month period. Specifically, CTP alleges that Respondent violated the Act by impermissibly selling cigarettes or smokeless tobacco to minors, on three separate dates, failing to verify, by means of photo identification containing a date of birth, that a purchaser was 18 years of age or older, on one of those dates, and utilizing a self-service display in a non-exempt facility, on two separate dates. For the reasons discussed below, I find in favor of CTP and impose an \$11,182 CMP against Respondent.

## I. BACKGROUND AND PROCEDURAL HISTORY

CTP began this matter by serving an administrative complaint, seeking an \$11,182 CMP, on Respondent at 2055 South Milford Road, Milford, Michigan 48381, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely filed an answer and denied the allegations.

On October 19, 2017, I issued an Acknowledgment and Pre-Hearing Order setting forth case procedures and exchange deadlines. On January 8, 2018, CTP filed its pre-hearing exchange, which included an Informal Brief of Complainant, and 20 exhibits (CTP Exs. 1-20). The 20 exhibits included the direct testimony, in the form of declarations, for two witnesses – Senior Regulatory Counsel Laurie Sternberg and Inspector Hiram Harris. Respondent did not file a pre-hearing exchange.

On March 19, 2018, I held a pre-hearing conference in this case. I explained to the parties that the purpose of an administrative hearing under the applicable regulations is to afford the parties an opportunity for cross-examination of exchange witnesses. I further explained that I must determine whether Respondent is liable for the violations alleged in the complaint as well as the appropriate penalty.

At the pre-hearing conference, Respondent declined to cross-examine CTP's witnesses, and admitted to the violations alleged in the complaint. However, Respondent requested a reduced penalty. I informed the parties that a hearing would not be required in this matter and I would make a decision based on the evidence of record. I also informed the parties that the decision, along with the parties' appeal rights, would be issued and sent to the parties, who could then appeal the decision to the Departmental Appeals Board if desired. I also admitted CTP's exhibits into the record.

The parties were given the opportunity to submit final briefs with any arguments they wish for me to consider. On April 16, 2018, Respondent filed its final brief (Resp. Final Brief). CTP did not file a final brief. As the briefing period is over, I now render my decision.

## II. ISSUES

- A. Whether Respondent sold cigarettes to a minor on August 11, 2017, in violation of 21 C.F.R. § 1140.14(a)(1); and
- B. Whether the penalty amount sought by CTP is reasonable.

### III. ANALYSIS

#### A. Violations

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the Act and implementing regulations at Part 21 of the Code of Federal Regulations. The Act prohibits the misbranding of tobacco products while they are held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k). FDA and its agency, CTP, may seek civil money penalties from any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 331(f)(9). The sale of tobacco products to an individual who is under the age of 18, the failure to verify the photographic identification of an individual who is not over the age of 26, and the use of a self-service display in a non-exempt facility are violations of implementing regulations. 21 C.F.R. §§ 1140.14(a)(1), (a)(2)(i), and § 1140.16(c).

CTP alleges that Respondent committed six violations of the Act and its implementing regulations within a 48-month period. Complaint at ¶ 1. Specifically, CTP alleges that, on August 11, 2017, Respondent sold cigarettes to a minor, and previously admitted to five violations of regulations found at 21 C.F.R. pt. 1140. *Id.* at ¶¶ 7, 10.

As indicated above, Respondent has admitted to the violation as alleged at the pre-hearing conference. As a result, I find Respondent is liable for six violations under the Act.

#### B. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent W.B.P. Enterprises, Inc. d/b/a Holden's Party Store 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, \$11,182, against Respondent for six violations of the Act and its implementing regulations within a 48-month period. Complaint at ¶ 1. Respondent has requested the penalty to be reduced to \$1,000. Resp. Final Brief at 2.

I find that Respondent committed six violations of the Act and its implementing regulations within a 48-month period. 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. § 333(f)(5)(B).

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

I find that Respondent committed three violations of selling cigarettes or smokeless tobacco to minors, one violation for failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and two violations for utilizing a self-service display in a non-exempt facility. 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.

**b. Respondent’s Ability to Pay And Effect on Ability to do Business**

Respondent has stated that the penalty amount is egregious. Answer at 2; Resp. Final Brief at 2. However, Respondent has not presented any evidence that it does not have the ability to pay the \$11,182 CMP sought by CTP.

**c. History of Prior Violations**

The current action is the fourth civil money penalty action that CTP has brought against Respondent. On March 6, 2017, CTP initiated the most recent CMP action, CRD Docket Number T-17-2439, FDA Docket Number FDA-2017-H-1082, against Respondent for five violations<sup>1</sup> of 21 C.F.R. pt. 1140 within a 36-month period. Complaint at ¶ 9. The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon penalty. *Id.* ¶ 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.

**d. Degree of Culpability**

Respondent suggests its employees should be held responsible for violations. Answer at 2; Resp. Final Brief at 2. Though I understand Respondent cannot be at its business all the time, it is Respondent’s responsibility to ensure its employees

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<sup>1</sup> Respondent’s prior violations include violations for sale to a minor on July 15, 2015 and September 8, 2016, failure to verify identification on September 8, 2016, and use of a self-service display in a non-exempt facility on December 20, 2013 and May 1, 2014.

comply with the law. I find that Respondent committed the six violations as alleged in the complaint, and I hold it fully culpable for all six violations of the Act and its implementing regulations.

#### **e. Additional Mitigating Factors**

Respondent has taken responsibility for its actions by admitting the violations. Respondent acknowledges that it “should be fined” but argues the penalty is egregious. Resp. Final Brief at 2. To prevent future violations, Respondent states it has upgraded its register system which now requires cashiers to enter the date of birth or scan newer licenses, it requires a manager/owner to double check all persons that are not 21 or older that wish to purchase cigarettes, it increased the signage around its establishment, and it has more frequent communication concerning its expectations with all register clerks. *Id.*

Respondent’s attempts to train employees and deter tobacco sales to minor are commendable. However, this is Respondent’s fourth CMP action, and Respondent has had ample opportunity to correct its violations and come into compliance, I find that a civil money penalty of \$11,182 is appropriate.

#### **IV. PENALTY**

Based on the foregoing reasoning, I find a penalty amount of \$11,182 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

#### **V. CONCLUSION**

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$11,182 against Respondent, W.B.P. Enterprises, Inc. d/b/a Holden’s Party Store, for six 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 48-month period.

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/s/  
Catherine Ravinski  
Administrative Law Judge