#### **Department of Health and Human Services**

#### DEPARTMENTAL APPEALS BOARD

#### **Civil Remedies Division**

Center for Tobacco Products, (FDA No. FDA-2015-H-3998)

Complainant

v.

Perring Auto Center, Inc. d/b/a Perring Sunoco,

Respondent.

Docket No. T-16-1678

Decision No. TB1628

Date: July 26, 2017

#### INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Perring Auto Center, Inc. d/b/a Perring Sunoco, located at 2535 Cleanleigh Drive, Parkville, Maryland 21234, 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 Respondent violated the Act by impermissibly selling a tobacco product to a minor. CTP also alleges that a default judgment was previously issued against Respondent for four violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,000 civil money penalty against Respondent.

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## **Procedural History**

CTP began this matter by serving an administrative complaint on November 10, 2015 by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely answered CTP's complaint. In his Answer, Respondent requested settlement discussions with CTP, but did not admit or deny the allegation nor provide any explanation or defense.

On May 9, 2016, by the direction of the administrative law judge assigned to this case on that date, the parties submitted a signed Case Management Order establishing certain procedural deadlines, including a hearing date of October 24, 2016. On August 23, 2016, Respondent filed an extension of time to produce discovery documents, which CTP did not oppose. CTP filed a motion on September 7, 2016, stating that Respondent had mailed discovery documents, and requesting that the hearing be postponed to give CTP time to receive and review the discovery documents.

This matter was transferred to me on September 8, 2016. On September 13, 2016, I issued a Pre-Hearing Order, cancelling all previously established deadlines and the October 24, 2016 hearing. The order re-established procedural deadlines, including deadlines for the parties to submit pre-hearing exchanges.

CTP filed its pre-hearing exchange on November 3, 2016, including an informal brief, witness and exhibit list, and twenty-two attachments. <sup>1</sup> CTP's pre-hearing exchange included the declarations of two witnesses. Respondent failed to file a pre-hearing exchange within the time prescribed.

On December 19, 2016, I issued an order scheduling a pre-hearing conference and extending the deadline for Respondent to file its pre-hearing exchange to January 4, 2017. I held a pre-hearing conference on January 24, 2017. During the pre-hearing conference, Respondent expressed his desire to settle this case. In a Joint Status Report filed January 25, 2017, the parties informed me that they were unable to reach a settlement. I held a second pre-hearing conference on January 31, 2017. During the pre-hearing conference, Respondent requested for relevant documents in this case to be translated into Korean. Copies of the translated documents were sent to Respondent on February 24, 2017. Respondent subsequently filed a pre-hearing brief on March 2, 2017.

<sup>&</sup>lt;sup>1</sup> These attachments were admitted into the record as CTP Exhibits 1-22. *See* Hearing Transcript at 10.

<sup>&</sup>lt;sup>2</sup> Respondent filed his pre-hearing brief one week after he received translated copies of the relevant documents in this case. So as not to prejudice Respondent, I will accept Respondent's late-filed pre-hearing brief into the record.

A hearing was held on March 8, 2017. During the course of the hearing, evidence was entered into the record and Respondent cross examined CTP's two witnesses. Respondent appeared pro se for the hearing and a Korean interpreter was provided for his assistance.

On April 7, 2017, I informed the parties that the Court had received both the English and Korean versions of the transcript of the hearing. I also set the deadline for the parties' post-hearing brief submissions as June 7, 2017. To date, neither party has filed a post-hearing brief.

## **Analysis**

#### I. Violations

CTP seeks to impose a civil money penalty against Respondent pursuant to the authority conferred by the Federal Food, Drug, and Cosmetic Act (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 and the failure to verify the photographic identification of an individual who is not over the age of 26 are violations of implementing regulations. 21 C.F.R. §§ 1140.14(a)(1), (a)(2)(i).

In its Complaint, CTP alleges that Respondent committed five violations of the Act and its implementing regulations within a thirty-six month period. A final default judgment has already been issued against Respondent for four of the violations. Thus, the only violation at issue is the alleged violation of 21 C.F.R. \$ 1140.14(a)(1) that was documented on July 20, 2015, at approximately 11:23 AM. Specifically, CTP stated in its Complaint that a person younger than 18 years of age was able to purchase a package of Newport cigarettes in Respondent's establishment at 2535 Cleanleigh Drive, Parkville, Maryland 21234.

Respondent's Answer did not admit or deny the alleged July 20, 2015 violation, nor did he offer any defense. In Respondent's Informal Brief, Respondent stated that he "admit[s] one violation; as for the other 4 instances, however, no concrete evidence such as receipts has been presented." Informal Brief of Respondent at 4.

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

<sup>&</sup>lt;sup>4</sup> See FDA-2015-H-0477. See also FDA-2014-H-0994.

It is unclear which violation Respondent admits, and which violations Respondent disputes. Respondent also asserted in his Informal Brief that he cannot afford a \$5,000 penalty, but did not offer any additional defense pertaining to the liability of the violation. *Id* at 6.

CTP's case against Respondent rests on the testimony of its witness, Jacob Smith, as well as its corroborating evidence. Complaint, CTP Exs. 1-22. Mr. Smith is an FDA-commissioned officer whose duties include determining whether retail outlets unlawfully sell tobacco products to minors in the state of Maryland. CTP Ex. 6 at 1-2. Mr. Smith's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id* at 2.

Mr. Smith testified that he went to Respondent's place of business on July 20, 2015, at approximately 11:23 AM. CTP Ex. 6 at 2. Mr. Smith further testified that on July 20, 2015, he confirmed that the minor was carrying her photographic identification, and that she did not have tobacco products in her possession. Mr. Smith testified that he saw the minor purchase a package of cigarettes from an employee of Respondent, and the employee did not provide the minor with a receipt after the purchase. *Id* at 3.

Mr. Smith stated that after the purchase, the minor and he both exited the store and returned to his vehicle, where the minor immediately gave him the pack of cigarettes. The cigarettes were observed to be a package of Newport cigarettes. CTP Ex. 6 at 3. Mr. Smith testified that he labeled the cigarettes as evidence, and took photographs of the package. *Id.* Mr. Smith testified that he then recorded the inspection in the FDA's Tobacco Inspection Management System. *Id.* 

Respondent has not specifically disputed the violation alleged by CTP to have occurred at his retail establishment on July 20, 2015, nor has he presented any defense. As a result, I find that the facts as outlined above establish Respondent Perring Auto Center, Inc. d/b/a Perring Sunoco's liability under the Act.

## **II. Civil Money Penalty**

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Perring Auto Center, Inc. d/b/a Perring Sunoco 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, \$5,000, against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint at 1.

In his Informal Brief, Respondent asserted that the penalty amount was inappropriate because Respondent is under financial hardship. Informal Brief of Respondent at 6.

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I have found that Respondent committed five violations of the Act and its implementing regulations within a thirty-six 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).

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

I have found that Respondent committed four violations of selling tobacco products to minors, and two violations for failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. 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 And Effect on Ability to do Business

On July 18, 2016, CTP sent Respondent a Request for Production of Documents. See CTP's motion for continuance and to extend deadlines filed on September 6, 2016. Included in CTP's request was a request for documents such as federal and/or state tax returns sufficient to identify Respondent's reported income for 2015. Respondent did not file a request for a protective order in response to CTP's request for production of documents. In fact, Respondent requested additional time to fully comply with CTP's request. In response to CTP's request, Respondent provided his and his spouse's personal income tax return for 2015.

<sup>5</sup> In the initial inspection of Respondent's establishment on September 18, 2013, one violation was documented for sale to a minor and one violation was documented for failure to verify the age of the person purchasing tobacco products. In accordance with customary practice, CTP counted the violations at this initial inspection as a single violation, and all subsequent violations as separate individual violations.



Respondent has consistently cooperated in providing information concerning his income. He has additionally sought to show his personal expenses and to explain the financial detriment and impact of his paying the full CMP that CTP seeks. Looking at the entire record, I find that the argument offered by Respondent is sufficient to establish that he lacks the wherewithal to pay the full \$5,000 civil money penalty. Respondent's combined income and asserted expenses are relevant to the issue of his ability to pay a penalty. Accordingly, I find that there is sufficient evidence to show that Respondent is incapable of paying the full penalty that is at issue here.

#### iii. History of Prior Violations

The current action is the third civil money penalty action brought against Respondent for violations of the Act and its implementing regulations. As noted above, Respondent has four times violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and twice violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i).

#### iv. Degree of Culpability

Based on my finding that Respondent committed the most recent violations in the current complaint, I hold him fully culpable for all five violations of the Act and its implementing regulations.

## v. Additional Mitigating Factors

Beyond Respondent's ability to pay, Respondent has presented no evidence concerning other mitigating factors that should justify a reduction in penalty amount.

## vi. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$3,000 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

# Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$3,000 against Respondent, Perring Auto Center, Inc. d/b/a Perring Sunoco, 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.

/s/ Margaret G. Brakebusch Administrative Law Judge