

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-1057)

Complainant

v.

Xiong Yan Weng  
d/b/a Dong Shun Grocery,

Respondent.

Docket No. T-17-2422

Decision No. TB2281

Date: December 7, 2017

**INITIAL DECISION**

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Xiong Yan Weng d/b/a Dong Shun Grocery, located at 1851 South 16th Street, Philadelphia, Pennsylvania 19145, 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 Dong Shun Grocery violated the Act by impermissibly selling cigarettes to minors, and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. CTP likewise alleges that Dong Shun Grocery previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140.

**Procedural History**

CTP began this matter by serving an administrative complaint seeking a \$5,501 civil money penalty on Respondent Dong Shun Grocery, at 1851 South 16th

Street, Philadelphia, Pennsylvania 19145, and 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. On April 4, 2017, I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges. CTP filed its pre-hearing exchange on July 25, 2017. Respondent filed its pre-hearing exchange on August 15, 2017. On September 14, 2017, Administrative Law Judge Margaret G. Brakebusch held a pre-hearing conference in this case. On November 13, 2017, both parties filed final briefs.

### **Decision on the Record**

Pursuant to 21 C.F.R. § 17.37(b), all direct testimony of witnesses shall be admitted in the form of a written declaration. In its pre-hearing exchange, CTP submitted two witness declarations, while Respondent Dong Shun Grocery submitted one witness declaration. During the pre-hearing conference, both parties waived their right to cross-examine proposed witnesses. The parties also agreed to waive their right to an oral hearing and proceed to submission of the case on the stipulated record. Therefore, I will decide this case on the basis of the written record. I have already admitted the all proposed exhibits into the record, designated as CTP Exhibits 1-14, and Respondent's Exhibits A, B-1, B-2, C, D, E-1, and E-2.

### **Analysis**

#### **I. Violations**

In its Complaint, CTP alleges that Respondent Dong Shun Grocery committed five violations of the Act and its implementing regulations within a thirty-six month period. CTP makes the following allegations:

- On April 22, 2015, CTP initiated a previous civil money penalty action, CRD Docket Number C-15-2132, FDA Docket Number FDA-2015-H-1284, against Respondent for three<sup>1</sup> 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, 1851 South 16th Street, Philadelphia, Pennsylvania 19145, on April 8, 2014, and November 6, 2014;

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<sup>1</sup> Two violations were documented on April 8, 2014, and two on November 6, 2014. 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.

- 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 6:53 PM on September 7, 2016, at Respondent’s business establishment, 1851 South 16th Street, Philadelphia, Pennsylvania 19145,<sup>2</sup> an FDA-commissioned inspector documented Respondent’s staff selling a package of Maverick Menthol 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 ¶¶ 8, 10-11; Informal Brief of Complainant at 2-3.

In order to prevail, CTP must prove Respondent’s liability by a preponderance of the evidence. The Supreme Court has described the preponderance of the evidence standard as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact’s existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Products of California, Inc. v. Construction Laborers*, 508 U.S. 602, 622 (1993).

Respondent, in effect, makes an argument that it has been denied due process because the gap in time between the alleged violations and notice of violations impeded Respondent’s ability to produce evidence. Specifically, Respondent was unable to review its video memory card, which only held 48 hours of recording. Respondent’s Informal Brief at 2. I note that CTP issued a Notice of Compliance Check Inspection to Respondent’s establishment on September 9, 2016, two days after the September 7, 2016 inspection. Complaint ¶ 9. I conclude that the gap in time between the alleged violations and notice of violations was not substantial enough to deny Respondent due process. I conclude that CTP provided reasonable

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<sup>2</sup> I note that the inspector’s narrative report lists the retail establishment as Ruby’s Food Market. CTP Exs. 10, 11. However, the inspector’s written declaration and CTP’s complaint lists the retail establishment as Dong Shun Grocery. CTP Ex. 8; Complaint ¶¶ 1, 8. All evidence presented by CTP indicates that the inspection on September 7, 2016, occurred at a retail establishment located at 1851 South 16th Street, Philadelphia, Pennsylvania 19145. Respondent also stated in its answer that its address is 1851 South 16th Street, Philadelphia, Pennsylvania 19145, and did not dispute ownership of the alleged retail establishment. I therefore conclude that the September 7, 2016, inspection occurred at Respondent’s retail establishment.

notice to Respondent of its alleged violations and Respondent was not denied due process.

Respondent denies the allegations in its pleadings, but has provided no evidence to refute that the violations on September 7, 2016, occurred. Based on the record as a whole, I conclude that CTP has established by a preponderance of the evidence that a minor entered Respondent's establishment and purchased a package of cigarettes from an employee on September 7, 2016. I also conclude that Respondent's staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. Therefore, I find that CTP has met its burden to establish Respondent Dong Shun Grocery's liability under the Act for five violations within a thirty-six month period.

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>3</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 Dong Shun Grocery 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, \$5,501, against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint ¶ 1. 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>3</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**

I have found that Respondent committed five violations of selling tobacco products to minors. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty should be set accordingly.

**ii. Respondent's Ability to Pay**

Respondent requests that its "financial situation be considered and the fine to be greatly minimized." Final Brief. Respondent states that a civil money penalty in the amount of \$5,501 would be "very detrimental to my financial stability." Respondent's Informal Brief at 3. Respondent states that he is "just a small business owner making [REDACTED] shown by my tax returns." *Id.* at 4. As part of the discovery process, Respondent filed a copy of his 2016 individual income tax return, [REDACTED]

[REDACTED] I will, however, take Respondent's statements into account when setting the penalty amount.

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

There is nothing in the evidentiary record that clearly establishes the effect a civil money penalty will have on Respondent's ability to do business. However, Respondent's statements with regard to that issue are sufficiently compelling to support a finding that justice requires some reduction of the penalty amount in this particular case.

**iv. History of Prior Violations**

The current action is the second civil money penalty action that CTP has brought against Respondent. 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.

