

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Vasudevay LLC  
d/b/a Town News and Tobacco,

Respondent.

Docket No. C-15-3873  
FDA Docket No. FDA-2015-H-3077

Decision No. CR4593

Date: April 26, 2016

**INITIAL DECISION**

I sustain the determination of the Centers for Tobacco Products of the United States Food and Drug Administration (CTP) to impose a civil money penalty of \$5,000 against Respondent, Vasudevay LLC, d/b/a Town News and Tobacco.

**I. Background**

Respondent requested a hearing in order to challenge CTP's determination to impose a \$5,000 civil money penalty against it. The parties rested their cases based on written submissions. CTP filed a brief and three proposed exhibits that are identified as CTP Ex. 1-CTP Ex. 3. Respondent filed a brief. I receive CTP Ex. 1-CTP Ex. 3 into the record.

## **II. Issues, Findings of Fact and Conclusions of Law**

### **A. Issues**

The issues are whether:

1. Respondent marketed and sold tobacco products in violation of federal law;
2. A civil money penalty of \$5,000 is reasonable.

### **B. Findings of Fact and Conclusions of Law**

CTP determined 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 (C.F.R.). 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). The Food and Drug Administration 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), (b)(1). Additionally, having a self-service display of tobacco products in a facility that allows access to minors is a violation of implementing regulations. 21 C.F.R. § 1140.16(c).

CTP alleges that Respondent committed multiple violations of the Act and implementing regulations and Respondent does not dispute CTP's allegations of noncompliance. CTP asserts, and Respondent admits, that Respondent sold tobacco products to minors on two occasions, failed to verify the purchaser's identification on one occasion, and maintained a self-service display of tobacco products in its facility on two occasions. Respondent's Answer; CTP Ex. 1. Specifically, on March 10, 2014 and again on May 6, 2015, Respondent sold tobacco products (cigarettes) to minor purchasers and, on March 10, 2014 failed to verify the minor's identification. CTP Complaint; CTP Ex. 2 at 1-2. Respondent had a self-service tobacco display in its facility on March 11, 2014, and October 9, 2013. CTP Ex. 2 at 2-4. The admitted violations add up to a total of five violations of the Act and implementing regulations over a period of about 19 months.

CTP bases its civil money penalty determination of \$5,000 on several factors. First, it argues that Respondent's noncompliance was egregious; constituting multiple violations of the Act and regulations over a sustained period of time

