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

notwithstanding the fact that Respondent had been warned explicitly against violating the law. Second, CTP asserts that Respondent's violations were serious because they involved selling a highly addictive and medically dangerous product to minors. Finally, CTP contends that the penalty of \$5,000 is not so large as to comprise an unduly onerous burden on Respondent. CTP points out that Respondent earned substantial profits in 2013 and 2014 (and and are respectively). CTP Brief at 8.

Respondent's only argument is to assert that a penalty of \$5,000 would have a substantial adverse financial impact on Respondent and its proprietor. Respondent's owner, Darshan Bhatt, acknowledges that his business made a profit but argues that all of the profits earned by Respondent go to pay his personal bills and expenses.

I do not find Respondent's argument to be a sufficient basis for reducing the civil money penalty amount. The undisputed facts are that Respondent egregiously violated the law and did so despite being warned not to. They show also that Respondent put the health and safety of minors at risk with its multiple violations. And, they show that Respondent has the wherewithal to pay the penalty amount despite its protestations to the contrary. Respondent earned substantial income in 2013 and 2014. It has not proven that its assets and financial resources are insufficient to pay the penalty amount.

/s/
Steven T. Kessel
Administrative Law Judge