

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Sharps Discount Liquors, Inc.
d/b/a Sharps Discount Liquors,

Respondent.

Docket No. T-17-2235
FDA Docket No. FDA-2017-H-0850

Decision No. TB2573

Date: March 29, 2018

INITIAL DECISION

I sustain the determination of the Center for Tobacco Products (“CTP”) of the United States Food and Drug Administration (“FDA”) to impose a civil money penalty of \$275 against Respondent, Sharps Discount Liquors, Inc. d/b/a Sharps Discount Liquors.

I. Background

Respondent requested a hearing in order to challenge CTP’s determination to impose a civil money penalty. I held a hearing by telephone on December 18, 2017. At the hearing, I received into evidence 19 exhibits from CTP, identified as CTP Ex. 1 – CTP Ex. 19. These exhibits include the written direct testimony of two witnesses, Senior Regulatory Counsel Laurie Sternberg (CTP Ex. 3) and FDA-commissioned Inspector Mella Baxter (CTP Ex. 4). Respondent offered no exhibits. Prior to the hearing, I received a brief from CTP and Respondent. Respondent also filed a post-hearing brief.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether:

1. Respondent sold tobacco products to minor purchasers in violation of federal regulations governing the sale of tobacco products; and
2. A civil money penalty of \$275 is a reasonable remedy.

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 sale of tobacco products to an individual who is under the age of 18 is a violation of implementing regulations. 21 C.F.R. § 1140.14(a)(1).

CTP premises its case on the results of inspections of Respondent's facility, conducted on May 11, 2016, and August 13, 2016. Ms. Baxter, an FDA-commissioned inspector, testified that on both occasions she went to Respondent's establishment accompanied by a minor who was employed for the purpose of attempting to purchase tobacco products from business establishments under inspection. CTP Ex. 4. Ms. Baxter testified that on each occasion she verified that the minor carried photographic identification that stated his or her age. *Id.* at ¶¶ 8, 13. On each occasion, Ms. Baxter watched the minor enter Respondent's establishment. *Id.* at ¶¶ 9, 14. Ms. Baxter testified that on each occasion she entered the establishment moments after, took a position from which she could observe the activities at the establishment's sales counter, and watched the minor purchase a pack of cigarettes from the clerk. *Id.*

CTP corroborated Ms. Baxter's testimony by offering as evidence photographs that Ms. Baxter made of the cigarettes that the minors purchased on the dates in question. CTP Exs. 8-9, 15-16. CTP also submitted narrative reports by Ms. Baxter created contemporaneously with each inspection. CTP Exs. 6, 13. Respondent offered no evidence to rebut Ms. Baxter's testimony.

Respondent argues that there is no evidence of a violation, that a photograph of cigarettes and the front of his store is not proof of a violation, and claims that it does not employ a clerk that meets the description provided by the inspector. Answer ¶ 3; R. Pre-Hearing Brief at 4; R. Post-Hearing Brief at 1.

However, Respondent's assertion that there is not sufficient evidence is a legal conclusion rather than an affirmative defense supported by evidence. Respondent's assertion that it does not employ a clerk that meets the description provided by the inspector is unsupported by any evidence of record. I afforded Respondent the opportunity to present evidence and that evidence could have included photographic or documentary exhibits or the written direct testimony of any supporting witnesses. Respondent did not avail itself of the opportunity that I gave it. I find no basis to conclude that any of Respondent's allegations are credible. Instead, I find evidence to support CTP's position. The contemporaneous narratives describes Respondent's clerk as being an adult female with black/dark brown hair for the May 11, 2016 inspection (CTP Ex. 6 at 2), and an adult female with blonde hair and glasses for the August 13, 2016 inspection (CTP Ex. 13 at 2). Although Respondent asserts, without support, that its clerks do not meet that description, Respondent concedes that one of its female clerks is "a brunette." R. Post-Hearing Brief.

CTP has proven that Respondent violated regulations governing the sale of tobacco products to minors, committing two violations during a period of less than one year. That is egregious conduct. Regulations authorize a penalty of up to \$275 for the violations committed by Respondent. 45 C.F.R. § 102.3; 21 U.S.C. § 333(f)(9).

The egregiousness of Respondent's conduct must amply justify the penalty amount. On two occasions within about three months, Respondent sold tobacco products to minor purchasers in violation of the law. It did so despite being warned by CTP after the May 11, 2016 violation that penalties would be imposed against Respondent for future unlawful sales. CTP Ex. 10.

I take notice that tobacco products are highly addictive and dangerous to the health of those who consume them. They may have lethal long-term effects on consumers. Younger purchasers are highly susceptible to becoming addicted. A penalty of \$275 is plainly reasonable given the dangers of tobacco products and Respondent's repeated unlawful sales of these products to minor purchasers.

/s/
Steven T. Kessel
Administrative Law Judge