

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Aadesh, Inc.
d/b/a 7 Eleven Store 25721A,

Respondent.

Docket No. T-17-1672
FDA Docket No. FDA-2017-H-0243

Decision No. TB2552

Date: March 23, 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 \$2,200 against Respondent, Aadesh, Inc., d/b/a 7 Eleven Store 25721A.

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 January 24, 2018. At the hearing, I received into evidence 33 exhibits from CTP, identified as CTP Ex. 1-CTP Ex. 33. These exhibits include CTP Ex. 14 (amended), the amended written declaration of Christopher Castiello. Respondent offered no exhibits. Prior to the hearing I received a brief from CTP. Respondent 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 and failed to check those purchasers' photographic identifications, in violation of federal regulations governing the sale of tobacco products; and
2. A civil money penalty of \$2,200 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 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) and (a)(2)(i).

CTP premises its case on the results of inspections of Respondent's facility, conducted on December 14, 2014, April 8, 2016, and June 22, 2016. Mr. Castiello, an FDA-commissioned inspector, testified that on all three occasions he 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. 14 (amended). Mr. Castiello testified that on each occasion he verified that the minor carried photographic identification that stated his or her age. On each occasion, Mr. Castiello watched the minor enter Respondent's establishment. Mr. Castiello testified that on each occasion he entered the establishment, took a position from which he could observe the activities at the establishment's sales counter, and watched the minor purchase a pack of cigarettes from the clerk. He testified that on December 14, 2014 and on April 8, 2016, the store clerk did not verify the minor's identification. He made no observation on June 22, 2016 as to whether the clerk verified the minor's identification. *Id.*

CTP corroborated Mr. Castiello's testimony by offering as evidence photographs that he made of the cigarettes that the minors purchased on the dates in question. CTP Ex. 20; CTP Ex. 25; CTP Ex. 30.

Respondent offered no evidence to rebut Mr. Castiello's testimony. In its post-hearing brief Respondent claims that there are "discrepancies" in Mr. Castiello's testimony that impeach his credibility. Respondent's post-hearing brief at 2. However, Respondent did not identify these alleged discrepancies. I discern no discrepancies between Mr. Castiello's written direct testimony and his cross-examination testimony that he gave at the January 24, 2018 hearing.

Respondent also made other assertions in its brief for which it failed to provide any evidence. It asserts that the video recording of the June 22, 2016 transaction shows that it was "done as per the proper procedure including the purchaser's ID check." It asserts also that Mr. Castiello was not in the store (apparently, on June 22, 2016) as he contended. It contends that, on June 22, 2016, Mr. Castiello had already left the store before the transaction completed. Respondent's post-hearing brief at 2-3.

These assertions are mere allegations unsupported by any evidence of record. I afforded Respondent the opportunity to present evidence and that evidence could have included the video recording that allegedly rebuts Mr. Castiello's testimony about the June 22, 2016 sale. Respondent did not avail itself of the opportunity that I gave it, nor did Respondent submit the written direct testimony of any supporting witnesses. I find no basis to conclude that any of Respondent's allegations are credible.

The evidence proves that Respondent repeatedly violated regulations governing the sale of tobacco products to minors, committing a total of four violations during a period of less than two years.¹ That is egregious conduct. Regulations authorize a penalty of up to \$2,200 for the violations committed by Respondent. 45 C.F.R. § 102.3

The egregiousness of Respondent's conduct amply justify the penalty amount. On multiple occasions Respondent sold tobacco products to minor purchasers in violation of the law. It did so despite being warned by CTP after the December 14, 2014 violations that penalties would be imposed against Respondent for future unlawful sales.

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.

¹ As a matter of administrative discretion CTP opted to count the sale of cigarettes to a minor purchaser on December 14, 2014 and the failure to check the purchaser's identification on that date as a single violation of the regulations governing tobacco sales. CTP issued a warning to Respondent based on the December 14, 2014 inspection results.

Younger purchasers are highly susceptible to becoming addicted. A penalty of \$2,200 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