

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Summerton Drugs Compounding and Dispensary LLC
d/b/a Summerton Drugs,

Respondent.

Docket No. C-15-2718
FDA Docket No. FDA-2015-H-1890

Decision No. CR4618

Date: May 26, 2016

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 \$500 against Respondent, Summerton Drugs Compounding and Dispensary, LLC, d/b/a Summerton Drugs

I. Background

Respondent requested a hearing in order to challenge CTP's determination to impose a \$500 civil money penalty against it. I held a hearing by telephone on March 15, 2016. At the hearing I received exhibits into evidence from CTP that are identified as CTP Ex. 1-CTP Ex. 10. I heard the cross-examination testimony

of Sharmane Anderson, an inspector working on behalf of CTP¹. Respondent offered no exhibits.

CTP filed a pre-hearing brief and a post-hearing brief in support of its position. Respondent filed a post-hearing brief.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether Respondent violated regulations governing the sale of tobacco products to minors and whether a civil money penalty of \$500 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). FDA 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).

There is no dispute that Respondent sells tobacco products to members of the public. Nor is there any dispute that, in the past, Respondent violated regulations prohibiting sales of tobacco products to minors. On December 3, 2014, Respondent signed an acknowledgement admitting that it had unlawfully sold cigarettes to a minor on September 30, 2013 and again on March 20, 2014. CTP Ex. 4.

What is in dispute in this case is whether Respondent sold tobacco products to a minor on a third occasion in violation of applicable regulations.

CTP premises its allegation of a third unlawful sale of tobacco products to a minor on Ms. Anderson's testimony and additional corroborating evidence.

¹ The transcript erroneously states that "James Naso" was sworn to testify. However, that witness did not appear in this case.

Ms. Anderson is an agent employed on CTP's behalf to inspect facilities that sell tobacco for possible violations of law. She testified that, on February 5, 2015, she visited Petitioner's establishment in the company of a minor who was under her direction and supervision. Ms. Anderson averred that, on that date, she entered Respondent's establishment shortly after the minor entered. CTP Ex. 2 at 3. She testified that, while inside the premises, she personally observed the minor purchase a package of cigarettes from one of Respondent's employees. *Id.* As corroborating evidence CTP produced a photograph of a package of Newport Non-Menthol Box cigarettes that the minor purchased on that date. CTP Ex. 9.

I find this evidence to be persuasive. Ms. Anderson was a credible witness and her testimony was not impeached on cross-examination. In particular, I find no basis to conclude that she was motivated to testify falsely nor do I find that she was incorrect in her assertion that she observed the sale. Moreover, the photograph of the package of cigarettes that the minor purchased on February 5, 2015, is more than ample corroboration of Ms. Anderson's testimony.

Respondent argues that this case boils down, essentially to a "he said, she said" situation in which Ms. Anderson's observations are contradicted by Respondent's denial that an unlawful sale took place. I disagree. Respondent has offered no evidence to contradict Ms. Anderson's testimony. It did not come forward with any witness testimony or other evidence rebutting Ms. Anderson's testimony. Furthermore, Respondent has not explained or rebutted the corroborating evidence offered by CTP, consisting of the photograph of the cigarettes offered by Respondent.

I find a civil money penalty of \$500 to be reasonable. Governing regulations authorize a maximum penalty of \$500. 21 C.F.R. § 17.2 A \$500 penalty is justified in this case by the egregiousness of Respondent's misconduct. The unlawful sale of a tobacco product to a minor on February 5, 2015, is Respondent's third violation of law in a period that is substantially less than two years' duration. Tobacco is a highly addictive and extremely dangerous product and selling to minors can only endanger the health and safety of these individuals. Respondent has not made a showing that it is unable to pay the penalty amount.

/s/

Steven T. Kessel
Administrative Law Judge