

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,
(FDA No. FDA-2017-H-6337)

Complainant,

v.

9 Muleys LLC
d/b/a Clark Fork Beverage / Cenex,

Respondent.

Docket No. T-18-276

Decision No. TB3036

Date: August 24, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) against Respondent, 9 Muleys LLC d/b/a Clark Fork Beverage / Cenex, located at 218 East 4th Street, Clark Fork, Idaho 83811, for three violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a 24-month period. Specifically, CTP alleges that Respondent violated the Act by impermissibly selling cigarettes or smokeless tobacco to minors, on three separate dates, and failing to verify, by means of photo identification containing a date of birth, that a purchaser was 18 years of age or older, on one of those dates.

I. BACKGROUND AND PROCEDURAL HISTORY

CTP began this matter by serving an administrative complaint, seeking a \$559 civil money penalty, on Respondent at 218 East 4th Street, Clark Fork, Idaho 83811, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely answered CTP's complaint denying the violations.

On November 21, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO) setting forth case procedures and exchange deadlines. On December 14, 2017, Respondent filed its pre-hearing exchange, which included an Informal Brief of Respondent (Resp. Informal Brief) and two unmarked documents. Respondent did not offer any witness testimony. On February 13, 2018, CTP filed its pre-hearing exchange, which included an Informal Brief of Complainant (CTP Informal Brief) and 13 exhibits (CTP Ex. 1-13). The 13 marked exhibits included the direct testimony, in the form of declarations, for two witnesses – Senior Regulatory Counsel Laurie Sternberg and Inspector Jeffrey Schraeder.

On May 3, 2018, I held a pre-hearing conference in this case. I explained to the parties that the sole purpose of an administrative hearing is to afford the parties an opportunity for cross-examination of the witnesses. Respondent communicated its desire to cross-examine Inspector Schraeder. On May 31, 2018, I held a hearing in this case. During the course of the hearing, Respondent cross-examined Inspector Schraeder, and I admitted CTP's exhibits into evidence.

On June 20, 2018, I made the hearing transcript available to the parties and set a July 23, 2018 deadline for post-hearing briefs. Respondent filed its post-hearing brief (Resp. Post-hearing Brief) on July 11, 2018, and CTP filed its post-hearing brief (CTP Post-hearing Brief) on July 20, 2018. In its post-hearing brief, CTP argues that Respondent's post-hearing brief attempts to present new evidence into the record, and that evidence should be excluded. CTP Post-hearing Brief at 2-4. CTP contends that Respondent's post-hearing brief includes written testimony that fails to comply with the regulations and my APHO. *Id.* I disagree. Respondent's post-hearing brief does not contain new evidence or sworn testimony but rather Respondent's final arguments. I find no reason to exclude it. CTP's Motion to Exclude is denied. As the briefing period is over, I now render my decision.

II. ISSUES

- A. Whether Respondent Clark Fork Beverage / Cenex sold cigarettes or smokeless tobacco to a minor on October 21, 2017, in violation of 21 C.F.R. § 1140.14(a)(1).
- B. Whether the penalty amount sought by CTP is reasonable.

III. ANALYSIS

A. Violations

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the Act and implementing regulations at Part 21 of the Code of Federal Regulations. 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)(1), (a)(2)(i).

CTP alleges that Respondent committed three violations of the Act and its implementing regulations within a 24-month period. Complaint at 1. Specifically, CTP alleges that, on October 21, 2017, Respondent sold smokeless tobacco to a minor, and previously admitted to two violations of the Act. *Id.* at 3-4, CTP Ex. 1. CTP's case against Respondent rests on the testimonies of Ms. Sternberg and Inspector Schraeder, and corroborating evidence.

Inspector Schraeder is an FDA-commissioned officer with the state of Idaho whose duties include determining a retailer's compliance with the age and photo identification requirements relating to the sale of tobacco products. CTP Ex. 4 at 1-2. His inspections entail accompanying trained undercover minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.* at 2

Inspector Schraeder testified that on October 21, 2017, he and a minor conducted an undercover buy compliance check inspection at Respondent's place of business, located at 218 East 4th Street, Clark Fork, Idaho 83811. *Id.* Before the inspection, Inspector Schraeder confirmed that the minor was under the age of 18, that the minor possessed his/her true and correct photographic identification, and that the minor did not have any tobacco products in his/her possession. *Id.* 2-3.

Inspector Schraeder testified that he parked his car near Respondent's establishment, and entered with the minor. He had a clear, unobstructed view of the sales counter, and observed the minor purchase smokeless tobacco from an employee at Respondent's establishment. *Id.*

After the transaction, Inspector Schraeder and the minor returned to the vehicle where immediately upon entering, the minor handed the inspector the smokeless tobacco purchased at Respondent's establishment. *Id.* Inspector Schraeder observed that the smokeless tobacco was Copenhagen Long Cut Wintergreen smokeless tobacco. *Id.* Inspector Schraeder processed the evidence according to procedure and completed a narrative report. *Id.*

Ms. Sternberg, Senior Regulatory Counsel for CTP's Office of Compliance and Enforcement, testified that the Copenhagen Long Cut Wintergreen smokeless

tobacco purchased during the October 21, 2017 inspection, was manufactured or processed for commercial distribution at facilities in Tennessee. CTP Ex. 3 at 3. The manufacturer of Copenhagen Long Cut Wintergreen brand smokeless tobacco does not have any production facilities in Idaho, where the smokeless tobacco was purchased. *Id.* at 3.

In its Answer, Respondent denied the allegations claiming it “reviewed the timeframe described by inspector J. Schraeder, via our surveillance system. There was no sale of Copenhagen by any employee during that time frame.” Answer at 1. Respondent also claimed it “can provide sworn statements and timecards from everyone that worked that day. Each of which watched the video of the hour during which the reported violations occurred.” Resp. Informal Brief at 7.

Respondent is essentially arguing that Inspector Schraeder’s testimony is untrue and the October 21, 2017 violation never occurred. Respondent’s defense rests entirely on an alleged surveillance video and the availability of witnesses. However, Respondent has not come forward with any witness testimony, employee timecards, or surveillance video to support its defense. Inspector Schraeder has testified under oath that he observed a minor purchase smokeless tobacco from an employee at Respondent’s establishment. CTP Ex. 3. Respondent has not presented any evidence to rebut Inspector Schraeder’s sworn testimony.

Based on the testimonies of both Inspector Schraeder and Ms. Sternberg, and CTP’s corroborating evidence, I find that Respondent sold smokeless tobacco to a minor on October 21, 2017, in violation of 21 C.F.R. § 1140.14(a)(1), and is liable for three violations of the Act.

B. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent is liable for a civil money penalty not to exceed the amounts listed in FDA’s civil money penalty regulations at 21 C.F.R. § 17.2. In its post-hearing brief, CTP requested I assess a \$2,236 civil money penalty against Respondent for four violations of the Act. CTP Post-hearing Brief at 5. However, in its Complaint, CTP only alleged three violations of the Act and sought a \$559 penalty, which is the maximum penalty amount for three violations.

I find that Respondent committed three violations of the Act and its implementing regulations within a 24-month period. When determining the amount of a civil money penalty, I am required to take into account “the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the

degree of culpability, and such other matters as justice may require.” 21 U.S.C. § 333(f)(5)(B).

a. Nature, Circumstances, Extent and Gravity of the Violations

I find that Respondent committed three violations of the Act. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

b. Respondent’s Ability to Pay And Effect on Ability to do Business

Respondent has not presented any evidence that it does not have the ability to pay the \$559 penalty sought by CTP nor has it presented any evidence regarding the effect on its ability to do business.

c. History of Prior Violations

The current action is the second CMP action brought against Respondent. On May 17, 2017, CTP initiated a previous CMP action, CRD Docket Number T-17-4094, FDA Docket Number FDA-2017-H-2921, against Respondent for two violations of 21 C.F.R. pt. 1140 within a 12-month period. CTP Ex. 1 at 1. CTP alleged that on June 18, 2016, Respondent sold tobacco products to a minor and failed to verify, by means of photo identification containing a date of birth, that the purchaser was 18 years of age or older. *Id.* at 4-5. On January 28, 2017, Respondent again sold tobacco products to a minor. *Id.* at 4.

Respondent argues that it was “falsely accused of the prior complaints.” Answer at 1. However, Respondent has already admitted that the prior violations¹ occurred, paid a penalty, and waived its right to contest such violations in subsequent actions. CTP Ex. 2. The prior violations are administratively final, and Respondent cannot contest them here. While Respondent has already paid a civil money penalty for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

¹ Two violations were documented on June 18, 2016, and one on January 28, 2017. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

