

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

Center for Tobacco Products,
Complainant

v.

Landover Services, Inc.
d/b/a US Fuel,
Respondent

FDA Docket No. FDA-2015-H-3859
CRD Docket No. T-17-377

Decision No. TB1040

Date: March 31, 2017

INITIAL DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a) as charged in the complaint; and
- 2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) as charged in the prior complaint; and
- 3) Respondent committed six violations in a forty-eight month period as set forth hereinabove.
- 4) Respondent is hereby assessed a civil penalty in the amount of \$9,000.

Glossary:

ALJ	Administrative Law Judge ¹
CMP	Civil Money Penalty
CTP/Complainant	Center for Tobacco Products
DJ	Default Judgment
FDCA	Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9)

¹ See 5 C.F.R. § 930.204.

FDA	Food and Drug Administration
HHS	Dept. of Health and Human Services
OSC	Order to Show Cause
POS	UPS Proof of Service
Respondent	Landover Services, Inc. d/b/a US Fuel
TCA	The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)(TCA)

I. JURISDICTION

I have jurisdiction to hear this case pursuant to my appointment by the Secretary of Health and Human Services and my authority under the Administrative Procedure Act (5 U.S.C. §§ 554-556), 5 U.S.C.A. § 3106, 21 U.S.C. § 333(f)(5), 5 C.F.R. §§ 930.201 et seq. and 21 C.F.R. Part 17.²

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint dated October 26, 2015 alleging that FDA documented six violations within a forty-eight month period.

Landover Services, Inc. d/b/a US Fuel (Respondent or US Fuel) was served with process on November 2, 2015 by the United Parcel Service. Respondent filed an Answer dated November 19, 2015.

A hearing was held on September 15, 2016. In a December 6, 2016 order, I instructed the parties to file Post Hearing Briefs by January 20, 2017. CTP filed a Post Hearing Brief on January 19, 2017. Respondent did not file a Post Hearing Brief.

² See also *Butz v. Economou*, 438 U.S. 478 at 513, 98 S.Ct. 2894, 57 L.Ed.2d 895 (1978); *Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980); *Federal Maritime Com'n v. South Carolina State Ports Authority*, 535 U.S. 743, 744 (2002).

III. BURDEN OF PROOF

The Center for Tobacco Products (CTP/Complainant) as the petitioning party has the burden of proof (21 C.F.R. § 17.33).

IV. LAW

21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1).

V. ISSUES

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1) as alleged in the complaint?

Is a civil penalty in the amount of \$11,000 appropriate?

VI. ALLEGATIONS

A. Agency's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name US Fuel, located at 6705 Martin Luther King Jr. Highway, Landover, Maryland 20785. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

During an inspection of US Fuel conducted on June 23, 2015, an FDA-commissioned inspector documented the following violations:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a).

Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes on June 23, 2015, at approximately 12:07 PM; and

b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(b)(1). Specifically, the minor's identification was not verified before the sale, as detailed above, on June 23, 2015, at approximately 12:07 PM.

B. Respondent's recitation of facts

Respondent appeared with counsel at the September 15, 2016, hearing and presented testimony.³ Respondent thereafter filed no Post-Hearing brief.

VII. Summary of Testimony and Evidence

All admitted testimonial and documentary evidence was reviewed and considered.

Only brief highlights are summarized herein.

1. Agency's Case

Josephine Laney

Josephine Laney (hereinafter "Laney") is an officer with the Alcohol and Drug Abuse Administration, Maryland Department of Health and Mental Hygiene, commissioned by the FDA to perform undercover buy and advertising and labeling inspections.

Laney's written declaration stated that on June 23, 2015, at approximately 12:07 PM, she conducted an inspection of Respondent's retail establishment doing business under the name US Fuel, located at 6705 Martin Luther King Jr. Highway, Landover, Maryland 20785. Before the inspection, Laney confirmed Minor 023 possessed her true

³ Tr. p.23, l. 12 to p. 31, l. 1.

and accurate photographic identification and did not have any tobacco products in her possession.

Laney accompanied Minor 023 into the establishment, and had an unobstructed view of the sales counter. Laney observed an employee of the establishment sell Minor 023 a package of cigarettes, and observed that prior to the purchase, Minor 023 did not present any identification to the employee.

Laney exited the store with Minor 023, and returned to her vehicle. Minor 023 immediately handed Laney the package of cigarettes, which she observed were Newport cigarettes. Laney documented and processed the evidence, and created a Narrative Report (CTP Ex. 15).

Laney also authenticated photographs taken during the inspection.

Laurie Sternberg

Laurie Sternberg (hereinafter “Sternberg”) is a Senior Regulatory Counsel in CTP’s Office of Compliance and Enforcement.

Sternberg’s written declaration stated that the tobacco product at issue in the June 23, 2015 inspection, Newport cigarettes, was manufactured in North Carolina and sold in interstate commerce. Sternberg also authenticated documents sent from CTP to Respondent.

2. Respondent’s Case

Abid Chaudhry

Abid Chaudhry (hereinafter “Chaudhry”) is part-owner of US Fuel.

Chaudhry testified at the hearing regarding measures taken since the violation on

June 23, 2015 to prevent future violations from occurring. Chaudhry put up signs and installed a point of sale system that requires the cashier to enter the date of birth when selling tobacco products. Chaudhry also testified that any employee that sells tobacco products to minors will be terminated.

3. Credibility determinations

All witnesses were found to be credible.

VIII. Analysis of Evidence and Testimony

Agency's case

CTP's supporting documentation for the violations above was admitted at the hearing without objection as Agency Exhibits 1 – 23.

CTP presented documents, photographs, and written declarations as evidence that on June 23, 2015, at approximately 12:07 PM, Laney conducted an inspection of Respondent's retail establishment, US Fuel, located at 6705 Martin Luther King Jr. Highway, Landover, Maryland 20785. Laney observed an employee of the establishment sell a package of Newport cigarettes to a person under the age of 18. Laney also observed that the minor's identification was not verified before the sale.

Respondent's case

Respondent offered no testimony or evidence in rebuttal to CTP's allegations of liability.

Respondent offered the testimony of Chaudhry to support mitigation of the amount of penalty. Chaudhry testified that new measures, including posting signs and updating the procedures for selling tobacco products, have been implemented to prevent

future violations.

IX. PRIOR VIOLATIONS

On March 10, 2015, CTP initiated a previous civil money penalty action, FDA Docket Number FDA-2015-H-0709, against Respondent for four (4) violations of 21 C.F.R. pt. 1140 within a twenty-four (24) month period. CTP alleged those violations to have occurred at Respondent's business establishment, 6705 Martin Luther King Jr. Highway, Landover, Maryland 20785.

The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and agreed to pay a monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions."

X. FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

The "relevant statute" in this case is actually a combination of statutes and regulations: The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (TCA), amended the Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) (FDCA) and created a new subchapter of that Act that dealt exclusively with tobacco products, (21 U.S.C. §§ 387-387u), and it also modified other parts of the FDCA explicitly to include tobacco products among the regulated products whose misbranding can give rise to civil, and in some cases criminal, liability. The 2009 amendments to the FDCA contained within the TCA also charged the Secretary of Health and Human Services with, among other things, creating regulations to govern tobacco

sales. The Secretary's regulations on tobacco products appear in Part 1140 of title 21, Code of Federal Regulations.

Under the FDCA, “[a] tobacco product shall be deemed to be misbranded if, in the case of any tobacco product sold or offered for sale in any State, it is sold or distributed in violation of regulations prescribed under section 387f(d).” 21 U.S.C. § 387c(a)(7)(B) (2012). Section 387 a-1 directed FDA to re-issue, with some modifications, regulations previously passed in 1996. 21 U.S.C. § 387 a-1(a)(2012). These regulations were passed pursuant to section 387f(d), which authorizes FDA to promulgate regulations on the sale and distribution of tobacco products; 75 Fed. Reg. 13,225 (March 19, 2010), codified at 21 C.F.R. Part 1140 (2015); 21 U.S.C. § 387f(d)(1) (2012). Accordingly, 21 C.F.R. 1140.1(b) provides that “failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.”

Under 21 U.S.C. § 331(k), “[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded” is a prohibited act under 21 U.S.C. § 331. Thus, when a Retailer such as Respondent misbrands a tobacco product by violating a requirement of 21 C.F.R. Part 1140, that misbranding in turn violates the FDCA, specifically 21 U.S.C. § 331(k). FDA may seek a civil money penalty from “any person who violates a requirement of this chapter which relates to

tobacco products.” 21 U.S.C. § 333(f)(9)(A) (2012). Penalties are set by 21 U.S.C. § 333 note and 21 C.F.R. § 17.2. Under current FDA policy, the first time FDA finds violations of 21 C.F.R. Part 1140 at an establishment, FDA only counts one violation regardless of the number of specific regulatory requirements that were actually violated, but if FDA finds violations on subsequent occasions, it will count violations of specific regulatory requirements individually in computing any civil money penalty sought. This policy is set forth in detail, with examples to illustrate, at *U.S. Food & Drug Admin., Guidance for Industry and FDA Staff, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions (Revised) (2015)*, available at <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf> [hereinafter *Guidance for Industry*], at 13-15. So, for instance, if a retailer sells a tobacco product on a particular occasion to a minor without checking for photographic identification, in violation of 21 C.F.R. §§ 1140.14(a) and (b)(1), this will count as two separate violations for purposes of computing the civil money penalty, unless it is the first time violations were observed at that particular establishment. This policy of counting violations has been determined by the HHS Departmental Appeals Board to be consistent with the language of the FDCA and its implementing regulations, see *CTP v. Orton Motor Company*, Departmental Appeals Board Decision number 2717 of June 30, 2016.

XI. LIABILITY

When a retailer such as Respondent is found to have “misbranded” a tobacco product in interstate commerce, it can be liable to pay a CMP. 21 U.S.C. §§ 331, 333. Respondent has submitted no evidence, nor made any argument in writing or at the hearing, to dispute liability as alleged in CTP’s Complaint.

Accordingly, I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a) in that a person younger than 18 years of age was able to purchase cigarettes on June 23, 2015.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(b) on that same date in that Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age.

The conduct set forth above on June 23, 2015 counts as two (2) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-15. Respondent has previously admitted to four violations of FDA policy in the relevant timeframe.

I find and conclude that Respondent is liable for six (6) violations of FDA policy in a forty-eight (48) month period.

XII. PENALTY

There being liability under the relevant statute, I must now determine the amount

of penalty to impose. My discretion regarding a penalty is constrained by regulation. I must determine the appropriate amount of civil money penalty, considering any mitigating or aggravating factors. 21 C.F.R. § 17.45 (b)(3).

In terms of specific punishments available, the legislation that provides the basis for assessing civil monetary penalties divides retailers into two categories: those that have “an approved training program” and those that do not. Retailers with an approved program face no more than a warning letter for their first violation; retailers without such a program begin paying monetary penalties with their first. TCA § 103(q)(2), 123 Stat. 1839, *codified at* 21 U.S.C. § 333 note. *See* 21 C.F.R. § 17.2. The FDA has informed the regulated public that “at this time, and until FDA issues regulations setting the standards for an approved training program, all applicable CMPs will proceed under the reduced penalty schedule.” FDA Regulatory Enforcement Manual, Aug 2015, ¶ 5-8-1. Because of this reasonable exercise of discretion, the starting point for punishments and the rate at which they mount are clear – the lower and slower schedules.

XIII. MITIGATION

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).

Respondent presented evidence in mitigation, over the objection of CTP. At the

hearing I reserved judgment on CTP's objection to the testimony. I hereby overrule CTP's objection. Respondent conceded the violations and the testimony, which was limited to mitigation, was material and relevant.

Respondent did not submit a Post-hearing Brief nor provide additional evidence and/or written statements to support mitigation of the civil money penalty.

Pursuant to 21 C.F.R. § 17.19(b)(17), I have the authority to "waive, suspend, or modify any rule" if I determine "that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law." The scope of the witness's testimony was limited to mitigation of the civil money penalty, specifically the steps taken by Respondent to prevent future violations from occurring. There is no reason to believe that the manner in which the direct testimony was taken impeded CTP's ability to effectively cross-examine the witness. CTP was offered the opportunity to cross-exam Respondent's witness and had no questions.⁴ I find and conclude that the testimony did not prejudice CTP. Accordingly, the direct testimony of Abid Chaudhry is hereby admitted into the record.

Respondent argued that since the June 23, 2015 violation, Respondent implemented new policies to prevent future violations including posting signs and requiring that cashiers enter the purchaser's date of birth into the point of sale system. I find that that these measures align with the purpose of the TCA to prevent unlawful sales of tobacco products to minors, and therefore justify reducing the penalty that CTP seeks to impose.

⁴ Tr. p. 31, ll. 2-5.

Respondent's efforts to prevent future violations, however, do not gainsay the fact that Respondent made unlawful tobacco sales to minors. Respondent is not only a repeat offender but has on multiple occasions sold a dangerously addictive product to minors, individuals who are among the most vulnerable in our society. Respondent has done so in the face of repeated warnings by CTP of the adverse consequences of unlawful sales of tobacco products and in the face of findings of prior violations of law. Taking into consideration the extent and gravity of the violations, as well as the mitigating factors, I find and conclude that \$9,000 is an appropriate civil money penalty.

XIV. CONCLUSION

Respondent committed six violations in a forty-eight month period and so, Respondent is liable for a civil money penalty of \$9,000. *See* 21 C.F.R. § 17.2.

WHEREFORE, evidence having read and considered it be and is hereby ORDERED as follows:

- a. I find Respondent has been served with process herein and is subject to this forum.
- b. I find Respondent committed six violations in a forty-eight month period.
- c. I assess a monetary penalty in the amount of \$9,000.

_____/s/_____

Richard C. Goodwin
U.S. Administrative Law Judge