

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-R-0153)

Complainant

v.

C K Food and Fuel MN Inc.
d/b/a C K Food and Fuel,

Respondent.

Docket No. T-17-1593

Decision No. TB1622

Date July 11, 2017

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a No-Tobacco-Sale Order against Respondent, C K Food and Fuel MN, Inc. d/b/a C K Food and Fuel, located at 4751 Nicollett Avenue, Minneapolis, Minnesota 55419, for six repeated 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 36-month period. The complaint alleges that C K Food and Fuel impermissibly sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, thereby violating the Act and its implementing regulations. The complaint likewise alleges that Respondent previously violated the Act by impermissibly selling tobacco products to minors, on three separate occasions, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, on three separate occasions.

The two original violations (OVs) for selling tobacco products to a minor and failing to check identification for age of the minor in this case occurred on July 23, 2013. Repeated violations (RVs) for sale to a minor and failure to check identification of a minor were documented on January 9, 2014, July 14, 2014, and February 16, 2016, for a total of 6 RVs within a period of 36 months.

Procedural History

CTP began this matter by serving an administrative complaint seeking a No-Tobacco-Sale Order for a period of 30 calendar days on Respondent, at 4751 Nicollett Avenue, Minneapolis, Minnesota 55419, 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. In its answer, Respondent stated that the cashier who made the sale in question on February 16, 2016 believed that the customer appeared to be an adult not under the age of 30.

CTP filed its pre-hearing exchange on April 28, 2017. CTP's pre-hearing exchange included the declaration of one witness, Inspector Steven Ploeckelmann. Respondent did not file a pre-hearing exchange.

On June 19, 2017, I held a pre-hearing conference in this case. I explained to the parties that the purpose of an administrative hearing under the applicable regulations is to afford the parties an opportunity for cross-examination of exchange witnesses. I further explained that I must determine whether Respondent is liable for the violations alleged in the Complaint as well as the appropriate penalty.

At the pre-hearing conference, Respondent did not dispute the facts of the case and admitted to the violations, expressly conceding liability. Respondent declined to cross-examine CTP's witness, stating that he did not dispute Inspector Ploeckelmann's findings on February 16, 2016, as reflected in his written testimony. However, Respondent requested a reduced penalty.

I informed the parties that a hearing would not be required in this matter and I would make a decision based on the evidence of record. The parties had no objections to the exhibits in the record, and they are now received and admitted into evidence. I also informed the parties that the decision, along with the parties' appeal rights, would be issued and sent to the parties, who could then appeal the decision to the Departmental Appeals Board if desired.

Analysis

I. Violations

CTP determined to impose a No-Tobacco-Sale Order on Respondent pursuant to the authority conferred by the Act. 21 U.S.C. § 333(f)(8). 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 a No-Tobacco-Sale Order against any person who commits repeated violations of the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 333(f)(8). 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).

In its complaint, CTP alleges that Respondent committed six repeated violations of the Act and its implementing regulations within a 36-month period. Complaint ¶ 1. Most recently, CTP alleges that Respondent sold tobacco products to a minor on February 16, 2016. Complaint ¶ 6. On that same date, CTP also alleges that Respondent failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. *Id.*

The facts of this case are not in dispute. As stated above, Respondent admitted to the violations as alleged in the complaint. *See also* Respondent's Answer. However, in its answer and during the pre-hearing conference, Respondent requested a reduced penalty and argued that CTP should not be granted a 30-day No-Tobacco-Sale Order. Respondent explained that, on February 16, 2016, his store clerk sold tobacco products to the customer in question because the clerk believed the minor was over 30 years old, thus, did not request photo identification.

I conclude that Respondent sold tobacco products to a minor on February 16, 2016, as Respondent does not dispute that the transaction in fact occurred. In regards to Respondent's failure to request photo identification, the store clerk's mistaken belief that the minor was over 30 years old is not a valid defense to this violation.

Retailers are required to verify by means of photographic identification containing the bearer's date of birth that no person purchasing a tobacco product is younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i). This requirement is not required when the purchaser is over the age of 26. 21 C.F.R. § 1140.14(a)(2)(ii). The regulations do not take into consideration the retailer's subjective belief that a purchaser is a particular age.

As a result, I find that the facts as outlined above establish Respondent C K Food and Fuel MN, Inc. d/b/a C K Food and Fuel's liable for six repeated violations under the Act.

II. No-Tobacco Sale Order

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for six repeated violations of the regulations found at 21 C.F.R. pt. 1140. The maximum period of time for the first No-Tobacco-Sale Order received by a retailer is 30 calendar days. *See* Pub. L. 111–31, div. A, title I, § 103(q)(1)(A), June 22, 2009, 123 Stat. 1838, 1839; Food & Drug Admin., Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers at 5-6, *available at* <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM252955.pdf> (last updated Dec. 15, 2016).

I have found that Respondent committed six repeated violations of the Act and its implementing regulations within a 36-month period. When determining the period to be covered by a No-Tobacco-Sale Order, 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).

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

I have found that Respondent committed six repeated violations including selling tobacco products to minors, on four separate occasions, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, on four separate occasions. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the duration of the No-Tobacco Sale Order should be set accordingly.

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

Respondent has stated that a 30-day No-Tobacco Sale Order would be unfair because it would destroy its business as tobacco sales are a primary source of revenue.

iii. History of Prior Violations

The current action is the third action brought against Respondent for violations of the Act and its implementing regulations.

On May 16, 2014, CTP initiated its first civil money penalty action, CRD Docket Number C-14-1095, FDA Docket Number FDA-2014-H-0608, against Respondent for

three¹ violations of 21 C.F.R. pt. 1140 within a twenty-four month period. Complaint ¶ 9. This first 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. *Id.* Respondent expressly waived its right to contest the violations in subsequent actions. *Id.*

On January 14, 2015, CTP initiated its second civil money penalty action, CRD Docket Number C-15-910, FDA Docket Number FDA-2015-H-0109, against Respondent for five violations of 21 C.F.R. pt. 1140 within a 36-month period. Complaint ¶ 10. The second action concluded when an Initial Decision and Default Judgment was entered on July 13, 2015, which found Respondent liable under the Act for the violations as alleged in the complaint. *Id.* The Initial Decision and Default Judgment became final on August 12, 2015.

In summary, Respondent impermissibly sold tobacco products to minors on July 23, 2013, January 9, 2014, July 14, 2014, and February 16, 2016. On those same dates, Respondent also failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older.

Respondent has already paid a civil money penalty for previous violations, and its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

iv. Degree of Culpability

Based on Respondent's admission, I find that Respondent committed the violations as alleged in complaint, and I hold it fully culpable for all of the violations of the Act and its implementing regulations.

v. Additional Mitigating Factors

Respondent asserts that it posts numerous signs warning that it will not sell tobacco products to minors, it has "zero tolerance" for employees who don't comply with its policy, and has long implemented extensive employee training to ensure compliance. Respondent's Answer at 2. However, I find these arguments to be unpersuasive to limit the penalty CTP seeks to impose.

¹ Two violations were documented on July 23, 2013, and two on January 9, 2014. In accordance with customary practice in civil money penalty actions, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations. Please note, that in No-Tobacco-Sale Order cases the violations are counted differently.

vi. Penalty

Based on the foregoing reasoning, I find a No-Tobacco-Sale Order for a period of 30 calendar days to be an appropriate penalty under 21 U.S.C. § 333(f)(5)(B) and 333(f)(8).

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment against Respondent, C K Food and Fuel MN, Inc. d/b/a C K Food and Fuel, in the form of a No-Tobacco-Sale Order for a period of 30 consecutive calendar days for six repeated 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 36-month period.

During this period of time, Respondent shall stop selling cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products regulated under the Federal Food, Drug, and Cosmetic Act. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

_____/s/
Catherine Ravinski
Administrative Law Judge