

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Three Star Market, Inc.
d/b/a Three Star Market,

Respondent.

Docket No. T-17-2918
FDA Docket No. FDA-2017-R-1617

Decision No. TB2545

Date: March 28, 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 six-month prohibition on the sale of tobacco products, no-tobacco-sale-order (“NTSO”), against Respondent, Three Star Market, Inc., d/b/a Three Star Market. Accordingly, I impose an NTSO against Respondent Three Star Market for a consecutive six-month period based on Respondent’s repeated violations of federal tobacco regulations over a period of 36 months.

I. Background

Respondent requested a hearing in order to challenge CTP’s determination to impose an NTSO against it. I held a hearing by telephone on January 9, 2018. At the hearing, I received into evidence 21 exhibits from CTP, identified as CTP Ex. 1-CTP Ex. 21. I received into evidence, one exhibit from Respondent – a collection of photographs – that I identified as Respondent’s Ex. 1. CTP and Respondent filed opening and closing

briefs. *See* CTP's Informal Brief ("Br."); CTP's Post-hearing Br.; Respondent's Informal Br.; Respondent's Post-hearing Br.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

1. Whether Respondent sold cigarettes or smokeless tobacco ("tobacco products") to a minor on January 21, 2017, in violation of 21 C.F.R. § 1140.14(a)(1).¹
2. Whether an NTSO of six months is reasonable.

B. Findings of Fact and Conclusions of Law

CTP determined to impose an NTSO 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).

The Act authorizes CTP to impose an NTSO prohibiting the sale of tobacco products at a retail outlet against any person who commits repeated violations of the regulations governing the offering and sale of tobacco products, including unlawful sales of tobacco products to minors. 21 U.S.C. §§ 333(f)(8); 387(f)(d). "Repeated violations" is defined as at least five violations of regulatory requirements over a 36-month period at a particular retail outlet. Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, § 103(q)(1)(A), 123 Stat. 1776, 1838 (2009), 21 U.S.C. § 333 note.

This case constitutes the fourth enforcement complaint filed by CTP against Respondent. The first three complaints are administratively final and their allegations are not contested.

On July 29, 2014, CTP filed an administrative complaint against Respondent alleging that Respondent unlawfully sold cigarettes to a minor and failed to verify the purchaser's age by means of photographic identification.² On September 9, 2014, Respondent admitted

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

² CTP in the current complaint inadvertently stated that it initiated the first CMP action against Respondent on July 28, 2014. *See* Complaint ¶ 9. CTP filed that Complaint on

the allegations in this complaint and waived its right to contest them. CTP Ex. 17. CTP filed a second administrative complaint against Respondent on May 12, 2015, again alleging that Respondent unlawfully sold cigarettes to a minor and failed to verify a purchaser's age by photographic identification. *See* Complaint ¶ 10; *see also* CRD Docket Number C-15-2231, FDA Docket Number FDA-2015-H-1394. On June 29, 2015, Respondent admitted to the allegations in the second complaint and waived its right to contest them. CTP Ex. 19. CTP filed a third administrative complaint against Respondent on July 22, 2016, and in this complaint, it sought imposition of a NTSO against Respondent. *See* Complaint ¶ 11; *see also* CRD Docket Number T-16-1396, FDA Docket Number FDA-2016-R-2146. Once again, CTP charged Respondent with unlawfully selling cigarettes to a minor and failing to verify the purchaser's age by photographic identification. The parties settled this matter and on September 20, 2016, Respondent agreed to a 21 day NTSO and waived its right to contest the allegations in the complaint. CTP Ex. 21.

In this fourth complaint, CTP alleges that, on January 21, 2017, Respondent once again unlawfully sold cigarettes to a minor purchaser. The evidence supports CTP's allegations.

CTP offered the testimony of an FDA-commissioned inspector, Ms. YaShica Ramsey. CTP Ex. 15. Ms. Ramsey testified that, on January 21, 2017, she went to Respondent's establishment accompanied by a minor. *Id.* ¶ 9. She confirmed that the minor had photographic identification establishing her actual date of birth and that she did not have tobacco products in her possession. *Id.* She accompanied the minor into Respondent's store and observed the minor purchase a package of cigarettes from the clerk. *Id.* at ¶ 10. CTP offered corroborating evidence consisting of photographs that Ms. Ramsey took of the outside of Respondent's store and the cigarettes purchased in Respondent's store by the minor purchaser. CTP Ex. 3; CTP Ex. 6-CTP Ex. 12.

Respondent offered no evidence to refute that which CTP presented. Respondent asserts that the minor purchaser may have looked older than her actual age. *See* Hearing Transcript ("Tr.") at 21; Respondent's Informal Br. at 6; Respondent's Post-hearing Br. at 2, 4. This is speculation, however. Respondent offered no witness to testify as to the minor's appearance. Respondent also asserts that its employee was "entrapped" into selling cigarettes to the minor. *See* Respondent's Post-hearing Br. at 2. However, it has offered no evidence to show that the sale of cigarettes on January 21, 2017, was anything other than an arm's length transaction between the clerk at Respondent's establishment and the minor purchaser. Respondent also complains that CTP should have been compelled to produce the minor purchaser as a witness. *See id.* at 2. However, although the minor's testimony would be relevant, she is not a witness in this case nor is her

July 29, 2014. *See* Complaint, CRD Docket Number C-14-1549, FDA Docket Number FDA-2014-H-1056.

testimony necessary. As I have discussed, Ms. Ramsey personally witnessed the unlawful sale on January 21, 2017, and produced corroborating evidence consisting of photographs of the cigarettes that Respondent sold to the minor on that date.

The evidence proves that Respondent repeatedly violated regulations governing the sale of tobacco products to minors, committing a total of seven repeated violations during a period of less than 36 months. That is egregious conduct and it amply merits the six-month NTSO that CTP determined to impose. Having found that Respondent contravened federal regulations governing the sale of tobacco products to minors, I now address the second issue before me: whether an NTSO of six months is reasonable.

NTSOs serve a dual purpose. An extremely important purpose is to protect the public from a retailer that has shown indifference to regulatory requirements through repeated violations of those requirements. I take notice that tobacco is a highly addictive product and that minors are extremely vulnerable to becoming addicted if they consume it. There is overwhelming proof that consumption of tobacco can, over time, be lethal. It is therefore in the public interest to protect individuals from retailers who persist in selling tobacco products to minor purchasers.

A second regulatory purpose of NTSOs is to deter retailers from unlawfully selling tobacco products. Potential prohibition against sale of these products should put retailers on notice that they will face a substantial penalty if they persist in violating the regulations.

A six-month NTSO is made reasonable in this case by Respondent's egregious conduct. Respondent's repeated violations – notwithstanding the imposition of remedies against Respondent that included a previous NTSO – clearly have done nothing to deter Respondent. Respondent persisted in selling tobacco products to a minor after receiving a warning from CTP and after having been subject to two civil money penalties and an NTSO. At this point, excluding Respondent from the market for tobacco products for a substantial period of six months is necessary because no other remedy has worked to deter Respondent from making unlawful sales.

Respondent argues that a six-month NTSO will effectively put it out of business. *See* Respondent's Post-hearing Br. at 1-3. However, it has not offered any evidence to substantiate that assertion. It also argues that it is the victim of targeted inspections, inspections aimed at minority business proprietors in poor communities. *See id.* at 2-3; *see also* Respondent's Informal Br. at 5-6. Respondent again offered no evidence to substantiate this claim.

Finally, Respondent asserts that the penalty should be mitigated by its efforts to prevent unlawful tobacco sales. *See id.* at 3. To that end, it points to numerous signs posted in its store that announce that Respondent will not sell tobacco products to minors. *See*

