

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-R-2993)

Complainant

v.

L and J Fill Up Inc.
d/b/a BP,

Respondent.

Docket No. T-16-2158

Decision No. TB2105

Date: October 20, 2017

INITIAL DECISION

I hereby impose a No-Tobacco-Sale Order against Respondent, L and J Fill Up Inc. d/b/a BP, for a period of 30 calendar days, for five repeated violations of federal tobacco regulations over a period of 36 months.

I. Background

The Center for Tobacco Products (“CTP”) seeks to impose a No-Tobacco-Sale Order (“NTSO”), for a period of 30 calendar days, against Respondent, L and J Fill Up Inc., d/b/a BP, located at 17776 Grand River Avenue, Detroit, Michigan 48227, for five 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 thirty-six (36) month period. CTP’s Complaint alleges that Respondent’s staff impermissibly sold tobacco products to minors and failed to verify that tobacco product purchasers were of

sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 301 et seq., and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140.

The complaint likewise alleges that Respondent BP previously admitted to four violations of regulations found at 21 C.F.R. pt. 1140. Specifically, CTP alleges that Respondent committed: (1) One original violation of sale to a minor and three repeated violations of 21 C.F.R. § 1140.14(a)(1)¹, on November 14, 2013, April 19, 2014, January 31, 2015, and December 6, 2015; and (2) One original violation and two repeated violations of failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, in violation of 1140.14(a)(2)(i), on November 14, 2013, April 19, 2014, and January 31, 2015. *See* Complaint ¶¶ 13-15; *see also* Informal Brief of Complainant at 9. Therefore, CTP seeks the imposition of an NTSO against Respondent for a period of 30 consecutive calendar days.

II. Procedural History

CTP began this matter by serving an administrative complaint, seeking an NTSO for a period of 30 calendar days, on Respondent, at 17776 Grand River Avenue, Detroit, Michigan 48227, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management.

On October 31, 2016, Respondent timely filed an Answer. In its Answer, Respondent conceded to multiple repeated violations of regulations found at 21 C.F.R. pt. 1140. *See* Answer ¶¶ 7, 13-14. However, Respondent denied the allegations that the "[Respondent] has committed a total of five repeated violations within a 36-month period." Answer ¶ 15.

On November 16, 2016, I issued an Acknowledgment and Pre-Hearing Order that set out the deadlines for the parties' submissions in this case, and issued informal briefs for the parties to complete and submit.²

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

² I note the following discovery matters concerning CTP's document requests. On December 30, 2016, CTP filed a Motion for a Protective Order. On January 17, 2017, Respondent filed a response to CTP's Motion for a Protective Order. On February 2, 2017, CTP filed a Motion to Compel Discovery. On February 3, 2017, I issued a Protective Order to govern the parties' document production and disclosure in this case. On February 21, 2017, Respondent filed a Response to CTP's Motion to Compel Discovery. In a March 8, 2017 letter, CTP was directed to file a status report indicating whether it had received Respondent's responses to its discovery requests and whether it was still seeking a ruling on the Motion to Compel Discovery in light of Respondent's

On March 8, 2017, CTP filed its pre-hearing exchange. CTP's pre-hearing exchange included an Informal Brief of Complainant, a list of proposed witnesses and exhibits, the declarations of two witnesses, and twenty-six (26) numbered exhibits. Respondent did not file a pre-hearing exchange.

On May 26, 2017, I held a pre-hearing conference in this case. During the pre-hearing conference, I explained that the sole purpose of a hearing under the applicable administrative regulations is to allow the parties an opportunity to cross-examine witnesses who provided sworn written testimony as part of the exchange. I further explained that Respondent was precluded from presenting any witnesses to offer sworn testimony at the hearing because it did not file a pre-hearing exchange. Respondent indicated that it wanted to cross examine only one of CTP's witnesses, Inspector YaShica Ramsey. Following the pre-hearing conference, I issued an Order that scheduled the hearing for July 6, 2017.

On July 6, 2017, I held a hearing in this case. During the course of the hearing, Respondent cross-examined Inspector Ramsey. *See* Hearing Transcript at 7-21. CTP then conducted a redirect examination of Inspector Ramsey. *See* Hearing Transcript at 22-24.

On August 4, 2017, I informed the parties that the Court had received the transcript of the hearing, and set the deadline for the parties' post-hearing brief submissions as September 5, 2017. Only Respondent filed a post-hearing brief ("Respondent's Brief"). As the briefing period is over, I now render my decision.

III. Issues

- A. Whether Respondent BP sold tobacco products to a minor, on December 6, 2015, in violation of 21 C.F.R. § 1140.14(a)(1).
- B. Whether the NTSO for a period of 30 calendar days that CTP seeks is reasonable.

IV. Applicable Regulations and Guidelines

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 Food and Drug Administration (FDA) and its agency, CTP, may seek the imposition of remedies against any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 331(f)(9).

response. On March 20, 2017, CTP filed a status report indicating that it had received Respondent's Response to its discovery request and that CTP no longer sought the Motion to Compel.

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), (2).

The Act provides for civil money penalties (“CMPs”) and NTSOs. NTSOs are authorized at 21 U.S.C. § 333(f)(8). The section allows for the imposition of an NTSO against a person who has committed “repeated violations” of restrictions on the sale of tobacco products. The term “repeated violations” is defined to mean “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet” *See* FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December 2016) at 3,5-6, *available at* <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.htm>. The Act also provides that “[p]rior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing” 21 U.S.C. § 333(f)(8).

The Act establishes the factors that must be considered in deciding on the length of an NTSO, but it does not specify the NTSO duration:

In determining the . . . period to be covered by a no-tobacco-sale order, the Secretary shall take into account the nature, circumstances, extent, and gravity of the . . . violations and, with respect to the violator, . . . , 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); *see also* *Kat Party Store, Inc., d/b/a Mr. Grocer Liquor Store*, CRD No. T-16-1684, at 2 (2016).

In addition, CTP developed policy guidelines that establish maximum NTSO durations. For a first NTSO, CTP recommends a maximum duration of 30 calendar days. *See* Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order: Guidance for Tobacco Retailers (August 2015) at 4, *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

I find that under 21 U.S.C. § 333(f)(8), I have the authority to impose an NTSO. While the CTP guidance notes are not regulations and thus, are not binding, as a matter of law, I consider them to be persuasive.

V. Analysis

A. Violations

CTP alleges that Respondent committed five repeated violations of the Act and its implementing regulations over a 36-month period. *See* Complaint at ¶ 1. CTP states that it did not include any repeated violations that occurred outside of the 36-month periods and any violations of other Act sections that are not at issue in this case. *Id.* at note 1. In its Complaint, CTP alleged that at approximately 11:47 a.m. on December 6, 2015, at

Respondent's business establishment, 17776 Grand River Avenue, Detroit, Michigan 48227, an FDA commissioned inspector documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age. Complaint ¶ 10; see Informal Brief of Complainant at 6.

Respondent concedes the past violations that were at issue in the two prior CTP Civil Money Penalty ("CMP") actions against Respondent. *See* Answer at ¶¶ 7, 13-14. Respondent denies the current violation, and denies that it allegedly "committed a total of five repeated violations within a 36-month period." *Id.* ¶¶ 1, 10, 15.

As Respondent has acknowledged that "there have been past violations," *see* Answer ¶ 7, I find that the only issue before me, concerning violations, is whether Respondent sold tobacco products to a minor, on December 6, 2015, in violation of 21 C.F.R. § 1140.14(a)(1), as alleged in the Complaint.

CTP's case against Respondent relies on the testimony of Inspector Ramsey who "accompanied by Minor 412, conducted an undercover buy portion of a follow-up compliance check inspection at BP," on December 6, 2015. Informal Brief of Complainant at 6. As evidence,³ CTP provided a sworn declaration of Inspector Ramsey. *See* Ramsey Declaration, CTP Ex. 6. Inspector Ramsey is an FDA-commissioned officer with Prevention Michigan. Her duties include conducting undercover inspections to determine whether retailers comply with "the age and photo identification requirements relating to the sale of tobacco." CTP Ex. 6 ¶¶ 2-3. CTP provided Inspector Ramsey's Narrative Report of the undercover inspection. Narrative Report, CTP Ex. 9. CTP also provided a redacted copy of the Minor 412's identification ("ID"). *See* CTP Ex. 11. Finally, Respondent cross-examined Inspector Ramsey at the July 6, 2017 hearing. *See* Hearing Transcript at 9 -21.

During the July 6, 2017 hearing, counsel for Respondent challenged the integrity of the undercover inspection by attacking the credibility of Minor 412. Respondent's sole argument is that the FDA cannot prove that Minor 412 was not carrying two IDs, the real one showing her actual age, and a second "fake" one showing that she was age 18 or older, because Inspector Ramsey never searched Minor 412 before the alleged sale took place to ensure that she was not carrying a second (fake) ID. *See* Respondent's Brief at 2; *see also* Hearing Transcript at 12-13. Accordingly, Respondent argues that Complainant failed to establish that Respondent violated 21 C.F.R. § 1140.14(a)(1), because Minor 412 could have shown the cashier at Respondent's establishment a fake ID showing that she was 18.

I find that Respondent's argument is speculative and misguided. Inspector Ramsey testified credibly and comprehensively about her observations during the December 6, 2015, inspection at which she observed Respondent selling tobacco products to Minor 412. *See* Hearing Transcript at 9 -21; Ramsey Declaration, CTP Ex. 6; Narrative Report, CTP Ex. 9. I will not recite every detail of Inspector Ramsey's testimony but will

³ The evidence discussed in this paragraph is not exhaustive.

highlight the points relevant to Respondent's contention regarding the possibility that the minor was carrying a "fake ID."

Inspector Ramsey testified that before the inspection at BP, she confirmed that Minor 412 had photographic identification showing her actual date of birth. *See* Ramsey Declaration, CTP Ex. 6 ¶ 9; Hearing Transcript at 12. During the cross-examination, Inspector Ramsey testified that she "verified" Minor 412's "own state ID." *Id.* at 13. She also confirmed that Minor 412 did not have any tobacco products in her possession. *Id.* Inspector Ramsey explained that inspectors "don't frisk minors." *Id.* Inspector Ramsey also testified that she accompanied Minor 412 into the gas station, that her standard operating practice is to stand directly behind the minor, and that sometimes she can hear the conversation between the minor and the cashier. *Id.* at 14. Inspector Ramsey testified that she observed the Minor 412 hand the attendant an ID, and assumed that it would be Minor 412's Michigan state issued ID.

This is the relevant excerpt of Inspector Ramsey's testimony during the cross-examination:

Q. Okay. I guess my question is, and this is for clarification, you're assuming that's what she showed. You do not recall seeing what ID it was?

A. She gave him an ID. I didn't try to verify it to make sure that she was not handing him a fake ID, but that wouldn't happen. They're trained to give their ID and they're trained to be honest. So the decoy would have no reason to give someone a fake ID.

Q. How do you know they're trained to do that? I thought earlier you said you weren't sure what training they went through?

A. Well, in this circuit, it says that the decoy has to have a state of Michigan ID. So I know that they are trained to show their ID, their state ID, not a fake ID.

Q. Okay.

A. So for them to have to -- for me to have to even verify that they have a state Michigan ID, that would mean that someone trained them to have a Michigan ID, the state of Michigan ID.

Q. Or if they didn't follow the procedures that they were given.

A. I've never heard of something like that happening. So I would bet my paycheck on it that that didn't happen in this case.

Hearing Transcript at 16 -17.

During the redirect examination conducted by CTP's counsel, Inspector Ramsey confirmed that it is her experience that when asked, under cover minors are required to "show their state ID that accurately reflects their age[.]" *See* Hearing Transcript at 23.

She further confirmed that she had no reason to believe that when asked, Minor 412 did not in fact, show the state ID that she show showed inspector Ramsey before the inspection at BP. *Id.*

Again, I find Inspector Ramsey's testimony to be credible. I find that CTP has provided an abundance of evidence to support its allegation that Respondent sold tobacco products to a Minor 412 on December 6, 2015, in violation of 21 C.F.R. § 1140.14(a)(1). I find that Respondent has failed to provide evidence to rebut CTP's allegation. Respondent was provided with sufficient opportunity to defend this case however, respondent failed to submit an Informal Brief, file an exchange, or provide witness testimony to rebut the evidence that CTP provided.

The facts as outlined above, establish that Respondent L and J Fill Up Inc. d/b/a BP is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; see 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1), no retailer may sell tobacco products to any person younger than 18 years of age.

B. No-Tobacco-Sale-Order Penalty

I now address the second issue before me -- whether an NTSO for a period of 30 calendar days is a reasonable penalty. The undisputed facts of this case show that Respondent is a repeated violator of FDA's tobacco regulations. Respondent has been the subject of two prior CMP actions. *See* CRD Docket Number C-15-148, FDA Docket Number FDA-2014-H-1658; CRD Docket Number C-15-5716, FDA Docket Number FDA-2015-H-1888. Between November 14, 2013 and December 6, 2015, Respondent sold tobacco products to minors on four occasions. *See* Complaint at 2, 5-6. On three of those occasions, Respondent failed to verify by means of photographic identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. *Id.* For the purposes of the instant NTSO action, CTP counted the violations that occurred on April 19, 2014, through December 6, 2015.

As previously mentioned, Respondent has conceded that the past violations occurred. Because Respondent already conceded the violations underlying the two previous CMPs, and as part of the settlement processes that concluded the prior CMPs, expressly waived its right to contest them in subsequent actions, there is no basis for questioning whether the current allegation is a repeat violation. Thus, Respondent committed a total of five repeated violations of FDA's tobacco regulations over a 36-month period.

CTP imposed two CMPs on Respondent but the CMPs did not deter Respondent from unlawfully selling tobacco products to minors. CTP now believes that, for Respondent's five repeated violations in less than 36 months, an assessment of a 30-day NTSO is

appropriate. Informal Brief of Complainant at 10. Respondent’s counsel argues that Respondent likely “acted in good faith when re[]lying on the potentially false ID when selling cigarettes to the minor in question” Respondent’s Brief at 2. Respondent further argues that in the alternative, should the Court issue an NTSO that “the length of the order should be significantly less than the 30 days sought by the Complainant.” *Id.*

When determining the period to be covered by an NTSO, 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).

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

I have found that Respondent committed a total of five repeated violations of FDA tobacco regulations within a period a 36-month period. The repeated inability of Respondent to comply with federal tobacco regulations and its “unwillingness or inability to correct the violations” is serious in nature. *See* Informal Brief of Complainant at 11. Thus, I find that an NTSO of thirty calendar days is a reasonable penalty.

2. Respondent’s Ability to Pay

This factor does not apply to the circumstances here because the penalty sought is exclusion (NTSO) and not a monetary penalty.

3. Effect on Ability to do Business

Respondent has not presented any evidence about the effect of a 30-day NTSO on its ability to conduct its business. I am not persuaded that the NTSO would severely hinder Respondent BP’s ability to continue other lawful retail operations during the NTSO period. Moreover, “the need to protect the [minors] outweighs the adverse effects that an NTSO may have on an individual retailer’s business, especially in light of the fact that imposition of this remedy is reserved only for those retailers who demonstrate indifference to the requirements of law.” *Kat Party Store, Inc., d/b/a Mr. Grocer Liquor Store*, CRD No. T-16-1684, at 3-4 (2016).

4. History of Prior Violations

It is undisputed that Respondent is a repeated violator of FDA’s tobacco regulations prohibiting the sale of tobacco products to minors. The current action is the first NTSO action against Respondent for violations of the Act and its implementing regulations. As noted previously, Respondent has been the subject of two prior CMP actions. In addition to the original violations on November 14, 2013, and the current violation on December 6, 2015, Respondent has twice violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and twice violated the requirement that retailers verify, by means of photo identification containing a

purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(b)(1). *See* Complaint ¶¶ 1, 13-15.

5. *Degree of Culpability*

Based on my finding that Respondent committed the most recent violation in the current complaint, I hold it fully culpable for all five repeated violations of the Act and its implementing regulations.

6. *Additional Mitigating Factors*

I do not find any mitigating factors. Respondent has not provided any evidence that it has implemented new policies for its employees about when to verify the age of tobacco product purchasers. Respondent has neither expressed a willingness to comply with the FDA tobacco regulations nor presented a plan for correcting its violations. Respondent has not expressed any remorse for the repeated violations.

VI. Penalty

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for five (5) 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 consecutive 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* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM252955.pdf> (last updated Dec. 15, 2016).

VII. Conclusion

For these reasons, I impose a No-Tobacco-Sale Order against Respondent L and J Fill Up Inc. d/b/a BP, for a period of 30 consecutive calendar days. 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