

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-R-3134)

Complainant

v.

Mansour Brothers Enterprises, Inc.
d/b/a Hyde Park Food Mart / Metro Market,

Respondent.

Docket No. T-17-4293

Decision No. TB2508

Date: March 19, 2018

INITIAL DECISION

I hereby impose a No-Tobacco-Sale Order (“NTSO”) against Respondent, Mansour Brothers Enterprises, Inc. d/b/a Hyde Park Food Mart / Metro Market (“Respondent”), 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 an NTSO, for a period of 30 calendar days, against Respondent, located at 900 West Kennedy Boulevard, Tampa, Florida 33606, for five repeated violations of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a 36-month period. CTP’s Complaint alleges that Respondent’s staff impermissibly sold cigarettes to minors, thereby violating 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 previously admitted to violations of regulations found at 21 C.F.R. pt. 1140. Specifically, CTP alleges that Respondent committed: (1) One original violation and three repeated violations of sale to a minor, in violation of 21 C.F.R. § 1140.14(a)(1)¹, on January 26, 2015, June 21, 2015, December 30, 2015, and October 4, 2016; and (2) One original violation and two repeated violations of failure to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth, in violation of 21 C.F.R. § 1140.14(a)(2)(i), on January 26, 2015, June 21, 2015, and December 30, 2015. *See* Complaint at ¶¶ 1, 9, 10; *see also*, Informal Brief of Complainant at 1-2. 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 900 West Kennedy Boulevard, Tampa, Florida 33606, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. DAB E-File Docket (Dkt.) #2b.

On May 23, 2017, Respondent timely filed an Answer ("Answer"). Dkt. #1. On May 31, 2017, I issued an Acknowledgment and Pre-Hearing Order ("APHO") that set out the deadlines for the parties' submissions in this case, and issued informal briefs for the parties to complete and submit. Dkt. #4.

On August 21, 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, and 19 numbered exhibits. CTP's exhibits included the declaration of one witness, Inspector Jose Ceballos. Dkt. #8-8t. On August 24, 2017, Respondent filed its pre-hearing exchange. Respondent's exchange included an Informal Brief, a list of witnesses and exhibits, and four marked exhibits which included five video clips at Exhibit 2. Respondent's exhibits included the written direct testimony of two witnesses, Jihad (Joseph) Mansour and Mutlu Kalinlioglu. Dkt. #9-9i.

On September 19, 2017, I held a pre-hearing conference in this case. During the prehearing conference, I explained that the sole purpose of a hearing under the applicable

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

regulations was to allow for the cross-examination and re-direct of any witnesses who had provided sworn testimony in pre-hearing exchanges, and only if the opposing party elected to cross-examine the witness. CTP advised of its intent to cross-examine Respondent's witnesses Mansour and Kalinlioglu. Respondent communicated her desire to cross-examine CTP's witness, Inspector Ceballos. *See* Dkt. #12.

On November 9, 2017, I held a hearing in this case. During the course of the hearing, I admitted the parties' exhibits. Respondent cross-examined Inspector Ceballos. *See* Hearing Transcript (Tr.) at 11-21. CTP then conducted a re-direct examination of Inspector Ceballos. *See* Tr. at 21-22. CTP waived cross-examination of Respondent's witnesses Mansour and Kalinlioglu. *Id.* at 22.

On November 20, 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 December 19, 2017. Also, the parties were given until December 19, 2017 to file any corrections to the transcript. Dkt. #15. On December 19, 2017, CTP and Respondent filed their respective post-hearing briefs. Dkt. ##16, 16a, and 17.

On December 19, 2017, by email transmission, CTP filed a request to seal and withhold from public disclosure Respondent's Exhibit 2, video clips 1-5. *See* Dkt. #18. Specifically, CTP requested "that all of these videos be placed 'under seal' and be withheld from public disclosure because they contain sensitive information and to protect the identity of CTP's undercover minor." *Id.*; citing, *CTP v. Beach Steil Inc. d/b/a 7-Eleven Store 32781*, CRD Docket No. T-17-221, FDA Docket No. FDA-2017-H-0835. On January 2, 2018, a letter by my direction was issued giving Respondent until January 17, 2018 to file a response to CTP's Motion to File Under Seal. Dkt. #19. On January 3, 2018, by email transmission, Respondent submitted its response, advising ". . . we have no objection to Complainant's request . . ." Dkt. #20. On January 19, 2018, I issued an Order granting CTP's motion and sealed from public disclosure Respondent's Exhibit 2, video clips 1-5 "until further order." Dkt. #21. As the briefing period is over, I now render my decision.

III. Issues

- A. Whether Respondent Hyde Park Food Mart / Metro Market sold cigarettes to a minor, on October 4, 2016, in violation of 21 C.F.R. § 1140.14(a)(1).
- B. Whether an NTSO for a period of 30 calendar days is reasonable.

IV. Applicable Regulations and Guidelines

CTP determined to impose an NTSO against Respondent pursuant to the authority conferred by the 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 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). 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 (*revised* December 2016) at 3,5-6, *available at* <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.htm>.

I find that under 21 U.S.C. § 333(f)(8), I have the authority to impose an NTSO.

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 footnote 1. In its Complaint, CTP alleged that at approximately 6:18 PM on October 4, 2016, at Respondent's business establishment, 900 West Kennedy Boulevard, Tampa, Florida 33606, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age. Complaint at ¶ 6; *see also*, Informal Brief of Complainant at 5.

Respondent concedes the past violations that were at issue in the two prior CMP actions against Respondent. See Answer at ¶¶ 8-10. Respondent denies the current violation, and denies that it allegedly "committed a total of five repeated violations within a 36-month period." *Id.* ¶¶ 1, 4, 6, 11.

As Respondent has acknowledged that “there have been past violations,” (*see* Answer at ¶¶ 8-10), I find that the only issue before me, concerning violations, is whether Respondent sold cigarettes to a minor, on October 4, 2016, 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 Ceballos who “conducted a follow-up undercover buy inspection at Respondent’s establishment located at 900 West Kennedy Boulevard, Tampa, Florida 33606, on October 4, 2016.” Informal Brief of Complainant at 5. According to Inspector Ceballos’ testimony, he “was accompanied by a confidential state-contracted minor, identified as FL-UP-16-41 (‘Minor FL-UP-16-41’).” *Id.* As evidence,² CTP provided a sworn declaration of Inspector Ceballos. *See* CTP Ex. 15, Ceballos Declaration. Inspector Ceballos is an FDA-commissioned officer with the Information Systems and Networks Corporation, a third-party contractor with the state of Florida. His duties include conducting “undercover buy (‘UB’) and advertising and labeling (‘A&L’) inspections required under FDA’s Tobacco Retail Inspection Contract with the state of Florida.” *Id.* at 1, ¶¶ 1-2. CTP provided Inspector Ceballos’ Narrative Report of the undercover inspection. CTP Ex. 4, Narrative Report. CTP also provided a redacted copy of the Minor FL-UP-16-41’s identification (“ID”). *See* CTP Ex. 5. Finally, Respondent cross-examined Inspector Ceballos at the November 9, 2017 hearing. *See* Tr. at 11-21.

During the November 9, 2017 hearing, counsel for Respondent challenged the integrity of the undercover inspection by attacking the credibility of Minor FL-UP-16-41. Respondent’s primary argument focused on verification of the minor’s ID and assertions that FDA cannot prove that Minor FL-UP-16-41 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. *See* Tr. at 12-14, 21; *see also*, Respondent’s Final Brief at 2. Accordingly, Respondent argues that Complainant failed to establish that Respondent violated 21 C.F.R. § 1140.14(a)(1), because “[t]here is, in fact, no acknowledgment that the sale took place only after scrutiny of the identification until admitted in Complainant’s Post Hearing Brief.” Respondent’s Final Brief at 2.

I find that Respondent’s argument is speculative and misguided. First and foremost, CTP’s Complaint did not allege a violation for failure to verify, by means of photographic identification, the age of a person purchasing cigarettes or smokeless tobacco (21 C.F.R. § 1140.14(a)(2)(i)) for the inspection conducted on October 4, 2016. The Complaint alleged only that, on October 4, 2016, “Respondent committed a violation of selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a)/1140.14(a)(1)” Complaint at ¶ 6. Inspector Ceballos testified credibly and comprehensively about his observations during the October 4, 2016, inspection at which he observed Respondent selling cigarettes to Minor FL-UP-16-41. *See* Tr. at 14-

² The evidence discussed in this paragraph is not exhaustive.

15, 17-18; CTP Ex. 4, at 1, Narrative Report; CTP Ex. 15, at 3, Ceballos Declaration. I will not recite every detail of Inspector Ceballos' testimony but will highlight the points relevant to Respondent's contention regarding the possibility that the minor was carrying a "fake ID."

Inspector Ceballos testified that before the inspection at Hyde Park Food Mart / Metro Market, he confirmed that Minor FL-UP-16-41 had photographic identification showing her actual date of birth. *See* CTP Ex. 4, at 1, Narrative Report; CTP Ex. 15, at 3, Ceballos Declaration; Tr. at 11-12, 13. During the cross-examination, Inspector Ceballos testified that he "verified" Minor FL-UP-16-41's identification. Tr. at 13, 14. Inspector Ceballos explained that inspectors do not search the undercover minors. *Id.* at 14. Inspector Ceballos also testified that he went into the establishment behind Minor FL-UP-16-41, that he "always say[sic] 10-15 feet away from where the minor is conducting the purchase so I have a good angle in order for me to of course, witness that purchase 100%." *Id.* Inspector Ceballos testified that he observed Respondent's sales clerk ask for identification, and that he observed Minor FL-UP-16-41 provide the sales clerk with identification. *Id.* at 18.

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

Q. Okay and when you pick her up what information do you provide to her?

A. The information is mostly I request that from her. Number one she is supposed to have an ID with her and no tobacco products whatsoever on her possession at the time before we go to conduct the inspection.

* * * * *

Q. And are you still working with her?

A. No, she's already – we call it aged out. She is already 18.

Q. And in fact on the day of the incident she was just a few months shy of her 18th birthday on that date, correct?

A. Based on the identification that's correct.

* * * * *

Q. And you confirmed that she had some sort of identification on her, correct?

A. That's the first thing I do when I pick [up] my minors, yes.

Q. Okay. And so how exactly do you do that? Do you just ask?

A. I ask the minors do you have your ID with you, and I see it yes.

Q. And is it possible that an informant can have more than one identification on them?

A. . . . I know at the time she had a driver's license, she was already driving.

Q. Is it possible that an informant can have more than one ID on their person? I mean you don't search them or anything right?

A. No ma'am. I don't do that. I ask them to and I have them of course show me the ID.

* * * * *

Q. Okay, and in that period of time again do you do any verification to see if there's any additional identification on the person?

A. No ma'am, because as I said before we do this before we go to do the inspections.

Tr. at 11-14, 21.

Again, I find Inspector Ceballos' testimony to be credible. I find that CTP has provided an abundance of evidence to support its allegation that Respondent sold cigarettes to Minor FL-UP-16-41 on October 4, 2016, 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. As part of its pre-hearing exchange, Respondent submitted the written Declarations of Jihad Mansour, Vice President, Secretary, and a Director of Mansour Brothers Enterprises, Inc.; and Mutlu Kalinlioglu, Respondent's Manager. Respondent Exs. 3 and 4. The Declarations submitted by Respondent do not address the October 4, 2016, inspection. Further, Respondent has failed to submit sufficient evidence which rebuts the allegation that Respondent sold cigarettes to Minor FL-UP-16-41 on October 4, 2016.

The facts as outlined above, establish that Respondent Mansour Brothers Enterprises, Inc. d/b/a Hyde Park Food Mart / Metro Market 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 cigarettes or smokeless tobacco 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 FDA Docket Number FDA-2015-H-3651; CRD Docket Number T-16-1108, FDA Docket Number FDA-2016-H-1800. Between January 26, 2015 and October 4, 2016, Respondent sold cigarettes or smokeless tobacco to minors on four occasions. See Complaint at ¶¶ 1, 8-10. On three of those occasions, Respondent failed to verify by means of photographic identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age. *Id.* For the purposes of the instant NTSO action, CTP counted the violations that occurred on June 21, 2015, and December 30, 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 a 36-month period, an assessment of a 30-day NTSO is appropriate. Informal Brief of Complainant at 11. Respondent's counsel argues for mitigation of the NTSO because, following the second CMP action:

Respondent acknowledged its responsibility and paid the requested penalty. This time, however, [Respondent] invested a significant amount of time, energy and money into assuring this would never happen again. [Respondent] completely changed its day to day operations and implemented the strongest, surest methods available to protect both its customers and itself from any errors in the future and safeguards were introduced to assure compliance

Respondent's Final Brief at 4. Respondent further argues that in the alternative, "[e]ven if this Court finds the Respondent liable based on the evidence, it still does not meet the

level of the requested sanction and Respondent should be permitted to operate in the responsible way it is required to operate, continue to upgrade when new safeguards become available and Petitioner go hence without a day.” *Id.* at 5.

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 36-month period. The repeated inability of Respondent to comply with federal tobacco regulations and its “unwillingness or inability to correct its violative actions” is serious in nature. *See* Informal Brief of Complainant at 12. Thus, I find that an NTSO of 30 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 Hyde Park Food Mart / Metro Market’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 January 26, 2015, and the current violation on October 4, 2016, Respondent has twice violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1),

and twice violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i). *See* Complaint at ¶¶ 1, 8-11.

5. *Degree of Culpability*

Based on my finding that Respondent committed the most recent violation as alleged 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's counsel asserts, among other things, that Hyde Park Food Mart / Metro Market's policy requires "every individual hired since December 2015 . . . to view the *Compliance Training for Tobacco Retailers* video, read the relevant requirements and sign a document acknowledging the employee's understanding of his or her responsibilities regarding tobacco sales before being added to the work schedule." Respondent's Final Brief at 3. While Hyde Park Food Mart / Metro Market may indeed have training programs that attempt to eliminate the illegal sale of cigarettes or smokeless tobacco to minors, these training programs have proven ineffective in Respondent's establishment. Because Respondent is a habitual violator of the FDA tobacco regulations, I find that a 30-day NTSO is necessary.

VI. Conclusion

For these reasons, I impose a No-Tobacco-Sale Order against Respondent Mansour Brothers Enterprises, Inc. d/b/a Hyde Park Food Mart / Metro Market, 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