Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2015-H-0499)

Complainant

v.

Quick Stop, L.L.C. / Rashid Sherwani d/b/a Quick Stop,

Respondent.

Docket No. C-15-1337

Decision No. CR4472

Date: December 1, 2015

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) against Respondent, Quick Stop, L.L.C. / Rashid Sherwani d/b/a Quick Stop, located at 1500 Corbin Avenue, New Britain, Connecticut 06053, for five 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 month period. Specifically, CTP alleges that Quick Stop violated the Act by impermissibly selling cigarettes to minors, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$5,000 civil money penalty on Respondent Quick Stop, at 1500 Corbin Avenue, New Britain, Connecticut 06053, 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, following an order granting an extension of time for the Respondent to file an answer. In its answer, Respondent did not actually deny the allegations, but instead contested the calculation of the number of violations, and the amount of the civil money penalty. On April 29, 2015, I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges. Following Motions by CTP, I issued an Order requiring Respondent to comply with CTP's Request for Production of Documents by August 10, 2015, and extending the parties' exchange deadlines. CTP filed its pre-hearing exchange on August 20, 2015. Respondent Quick Stop subsequently timely filed its pre-hearing exchange, admitting all allegations in the Complaint but contesting the amount of the civil money penalty.

Decision on the Record

Pursuant to 21 CFR § 17.37(b), all direct testimony of witnesses shall be admitted in the form of a written declaration. In its pre-hearing exchange, CTP submitted two witness declarations. Respondent Quick Stop has not submitted direct testimony, nor has it requested to cross examine CTP's witnesses. Because Respondent Quick Stop has not submitted any direct testimony, there is no one for CTP to request to cross-examine. And, since Respondent Quick Stop has admitted all the allegations in the Complaint, the witness declarations that CTP has submitted are not relevant to the issue of the amount of the civil money penalty. Therefore, I will decide this case on the basis of the written record.

Analysis

I. Violations

In its Complaint, CTP alleges that Respondent Quick Stop committed five violations of the Act and its implementing regulations within a thirty-six month period. On April 27, 2015, Quick Stop filed an answer to the Complaint contesting the amount of the civil money penalty. Answer. Additionally, on September 10, 2015, Quick Stop filed an informal brief, admitting all the allegations in the Complaint, but contesting the amount of the civil money penalty. Informal Brief of Respondent.

CTP makes the following uncontested allegations:

• CTP previously issued a warning letter to Respondent Quick Stop on July 5, 2012, citing violations¹ of 21 C.F.R. pt. 1140 on May 3, 2012, at Respondent's business establishment, 1500 Corbin Avenue, New Britain, Connecticut 06053;

¹ In the complaint, CTP describes the action or actions that took place at Respondent Quick Stop's business establishment on May 3, 2012, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint dated December 30, 2013, and attached to the present complaint, however, CTP described two discrete

- On January 24, 2014, CTP initiated a previous civil money penalty action, CRD Docket Number C-14-476, FDA Docket Number FDA-2013-H-1701, against Respondent Quick Stop for three violations of 21 C.F.R. pt. 1140 within a 24-month period.² CTP alleged those violations to have occurred on May 3, 2012, and July 23, 2013;
- The previous action concluded when Rashid Sherwani, Respondent's authorized representative, settled the claims on Respondent's behalf. Mr. Sherwani signed an Acknowledgment Form dated March 8, 2014 in which he "admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on March 28, 2014;
- During a subsequent two-part inspection of Respondent's business establishment, at approximately 10:53 a.m. on September 23, 2014, at Respondent's business establishment, 1500 Corbin Avenue, New Britain, Connecticut 06053, FDA-commissioned inspectors documented Respondent's staff selling a package of Pall Mall Orange cigarettes to a person younger than 18 years of age. The inspectors also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

CTP asserts that these allegations, as supported by documentary evidence, are sufficient to establish a basis for liability against Respondent.

Respondent Quick Stop has not disputed these allegations. Therefore, I find that these facts establish Respondent Quick Stop, L.L.C. / Rashid Sherwani d/b/a Quick Stop's liability 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. § 387f(d); *see* 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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic

violations at Respondent Quick Stop's business establishment on May 3, 2012: a violation of 21 C.F.R. § 1140.14(a), a and a violation of 21 C.F.R. § 1140.14(b)(1). Therefore, I will infer that CTP's description in the present complaint of "a violation" occurring on May 3, 2012, was a typographical error.

² The Respondent's name in the prior complaint was "Quick Stop, L.L.C."

identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.

A. II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Quick Stop is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the maximum penalty amount, \$5,000, against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint ¶ 1. In its Informal Brief, CTP continues to assert that a \$5,000 civil money penalty is appropriate. Informal Brief of Complainant at 11.

Respondent Quick Stop argues "that CTP is pursuing to apply two segments of law per violation to make the offence look more heinous." Informal Brief of Respondent. Respondent goes on to state that "[t]his practice, although it may be legal, has an enormous impact on our business." *Id.* Essentially Respondent is arguing that CTP should charge only one violation per inspection. CTP's practice of charging more than one violation per inspection is not inconsistent with the regulations.

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. § 303(f)(5)(B).

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

Time and again, Respondent Quick Stop has failed to comply with the Act and its implementing regulations. Respondent admitted to two violations for selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and two violations for failing to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(b)(1). The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

ii. Respondent's Ability to Pay

CTP is seeking a \$5,000 civil money penalty against Respondent Quick Stop. In its production of documents, Respondent Quick Stop provided CTP with tax returns for 2012, 2013 and 2014. CTP states that Respondent reported a gross profit of over each year. Additionally, CTP states that the tax returns showed yearly net earnings from self-employment that increased from the in 2012, to the in 2013, and to the states in 2013.

in 2014. CTP also asserts that in 2014 Respondent's capital accounts had a year-end balance of **Example**.

Respondent states that the proposed penalty "would mean that we will lose approximately 25% of our net **annual** earnings. This is a huge number for us, or for any business." Informal Brief of Respondent. Additionally, Respondent further explained the tax returns submitted by CTP. *Id.* Respondent explained that the capital account that CTP references included both cash and inventory, and that operating the business with that amount of cash has "been very, very tough and you can imagine taking out \$5,000.00 from it would mean we can no longer run our business as we won't be able to pay our bills in time and won't be able to pay for our inventory." *Id.*

Considering Respondent's explanation of these figures, imposition of a \$5,000 penalty would take away nearly a quarter of Respondent's net annual income, a severe punishment.

iii. Effect on Ability to do Business

There is nothing in the evidentiary record that shows the effect a civil money penalty will have on Respondent Quick Stop's ability to do business. CTP asserts that "Respondent did not provide evidence that this penalty will prevent Respondent from conducting business. The likely result may simply be lower profits for 2015." Informal Brief of Complainant. Respondent stated that this penalty would mean it could not pay its bills on time and would not be able to pay for its inventory. Informal Brief of Respondent. While the record does not include specific evidence to show the effects of a \$5,000 civil money penalty, it appears that a civil money penalty of this amount will have a substantial effect on Respondent's ability to do business.

iv. History of Prior Violations

The current action is the second civil money penalty action brought against Respondent Quick Stop within the past thirteen months for violations of the Act and its implementing regulations. In the first civil money penalty action, CRD Docket Number C-14-476, FDA Docket Number FDA-2013-H-1701, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on May 3, 2012, and July 23, 2013. On those same dates, 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. 21 C.F.R. § 1140.14(b)(1). Respondent settled these claims with CTP for an undisclosed penalty amount.

The current action "brings Respondent's total violation count to three sales to a minor, in violation of 21 C.F.R. § 1140.14(a), and three failures to verify the identification of

persons who were not over the age of 26, in violation of 21 C.F.R. § 1140.14(b)(1)." Informal Brief of Complainant. I agree with CTP that "[t]hese repeat violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations." *Id.* While Respondent has already paid a civil money penalty for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

v. Degree of Culpability

Respondent Quick Stop admitted to all violations in its informal brief. Based on Respondent Quick Stop's own admissions, I hold it fully culpable for all six violations of the Act and its implementing regulations.³

vi. Additional Mitigating Factors

Respondent Quick Stop stated that it has taken steps to prevent future violations. Specifically, Respondent states that: everyone has been trained using the "WeCard" program, Respondent has developed a store tobacco policy and affixed it by the counter in sight of the cashier, and that this penalty and correspondence is shared with all employees "so they actually understand the severity and magnitude of consequences." Informal Brief of Respondent.

vii. Penalty

I acknowledge the financial strain a large penalty amount will have on Respondent's small business, as well as the steps taken by Respondent to ensure additional future violations are not found. Based on the foregoing reasoning, I find a reduced penalty amount of \$2,500 to be appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$2,500 against Respondent, Quick Stop, L.L.C. / Rashid Sherwani d/b/a Quick Stop, for five 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 month period.

/s/

Catherine Ravinski Administrative Law Judge

³ I note that CTP's requested civil money penalty is based upon 5 violations.