

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-2237)

Complainant

v.

Vicente Cruz
d/b/a ENR Market,

Respondent.

Docket No. C-15-708

Decision No. CR4050

Date: July 16, 2015

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Vicente Cruz d/b/a ENR Market, located at 431 Zion Street, Hartford, Connecticut 06106, for eight 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 forty-eight month period. Specifically, CTP alleges that ENR Market violated the Act by impermissibly selling cigarettes to minors, failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and selling individual cigarettes.

Procedural History

CTP began this matter by serving an administrative complaint seeking an \$11,000 civil money penalty on Respondent ENR Market, at 431 Zion Street, Hartford, Connecticut 06106, 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 admitting the allegations but contesting the amount of the civil money penalty. On February 5, 2015, I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges. CTP filed its pre-hearing exchange on May 19, 2015. Respondent ENR Market subsequently timely filed its pre-hearing exchange, admitting all allegations in the Complaint but contesting the amount of the civil money penalty.

On May 18, 2015, CTP filed a Motion for Partial Summary Decision, seeking a judgment solely on Respondent ENR Market's liability. Respondent's response to the Motion was due on or before June 17, 2015. As of the date of this decision, Respondent has not filed a response to CTP's Motion for Partial Summary Decision.

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 Motion for Partial Summary Decision, CTP submitted one witness declaration, but did not provide any additional witness declarations or a witness list in its pre-hearing exchange. Respondent ENR Market has not submitted direct testimony, nor has it requested to cross examine CTP's sole witness. Because neither party has requested to cross-examine an opposing party's witness, the evidentiary record is considered complete. Therefore, I will decide this case on the basis of the written record. In light of the decision now being issued, CTP's May 18, 2015 Motion for Partial Summary Decision is now moot.

Analysis

I. Violations

In its Complaint, CTP alleges that Respondent ENR Market committed eight violations of the Act and its implementing regulations within a forty-eight month period. On January 20, 2015, ENR Market filed an answer to the Complaint admitting all the allegations but contesting the amount of the civil money penalty. Answer. Additionally, on June 10, 2015, ENR Market filed an informal brief, once again admitting all the allegations but contesting the amount of the civil money penalty. Informal Brief of Respondent.

CTP makes the following uncontested allegations:

- At approximately 2:42 p.m. on August 7, 2012, at Respondent ENR Market's business establishment, 431 Zion Street, Hartford, Connecticut 06106, an FDA-commissioned inspector observed Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18

years of age. The inspector also observed 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 Ex. 6 ¶ 3.

- In a warning letter dated November 8, 2012, CTP informed Respondent of the inspector's August 7, 2012, observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action. *Id.* ¶¶ 1-2.
- At approximately 10:11 a.m. on January 29, 2013, at Respondent ENR Market's business establishment, 431 Zion Street, Hartford, Connecticut 06106, FDA-commissioned inspectors observed Respondent's staff selling a box of Maverick Menthol Box 100s cigarettes to a person younger than 18 years of age. The inspectors also observed 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 Ex. 3 ¶ 1.
- In a complaint dated August 19, 2013, CTP initiated its first civil money penalty action, CRD Docket Number C-13-1017, FDA Docket Number FDA-2013-H-0844, against Respondent ENR Market for three violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred on August 7, 2012¹, and January 29, 2013. *Id.*
- The first action concluded when Respondent, Vicente Cruz, settled the claims. On August 23, 2013, Mr. Cruz signed an Acknowledgment Form in which he acknowledged the violations occurred, waived his ability to contest the violations in the future, and stated that he understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions. CTP MSD Ex. A.
- At approximately 9:52 a.m. on October 21, 2013, at Respondent ENR Market's business establishment, 431 Zion Street, Hartford, Connecticut 06106, FDA-commissioned inspectors observed Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age. The inspectors also observed that staff sold individual cigarettes. Complaint Supporting Documents/Exhibits ¶ 1.

¹ "For the purposes of calculating the penalty, FDA counted all the violations found during the initial inspection on August 7, 2012 as a single violation, and all subsequent violations as separate violations." Informal Brief of Complainant at 8-9.

- In a complaint dated April 2, 2014, CTP initiated its second civil money penalty action, CRD Docket Number C-14-870, FDA Docket Number FDA-2014-H-0378, against Respondent ENR Market for five violations of 21 C.F.R. pt. 1140 within a 36-month period. CTP alleged those violations to have occurred on August 7, 2012, January 29, 2013, and October 21, 2013. *Id.*
- The second action concluded when Administrative Law Judge Scott Anderson issued an Initial Decision and Default Judgment on June 3, 2014, “accepting the facts alleged in the Complaint as true” and finding “those facts establish Respondent’s liability under the ACT.” The judgment became binding on Respondent on July 3, 2014. CTP Ex. 4.
- At approximately 9:09 a.m. on August 5, 2014, at Respondent ENR Market’s business establishment, 431 Zion Street, Hartford, Connecticut 06106, FDA-commissioned inspectors documented Respondent’s staff selling a single cigarette 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. Complaint ¶ 1.
- In a complaint dated December 18, 2014, CTP initiated its third and current civil money penalty action, CRD Docket Number C-15-708, FDA Docket Number FDA-2014-H-2237, against Respondent ENR Market for eight violations of 21 C.F.R. pt. 1140 within a 48-month period. CTP alleged those violations to have occurred on August 7, 2012, January 29, 2013, October 21, 2013, and August 5, 2014. *Id.*

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

Respondent ENR Market has not disputed these allegations. Therefore, I find that these facts establish Respondent Vicente Cruz d/b/a ENR Market’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 identification containing a purchaser’s date of birth, that no cigarette purchasers are younger

than 18 years of age. Finally, under 21 C.F.R. § 1140.14(d), no retailer may sell individual cigarettes.

A. II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent ENR Market 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, \$11,000, against Respondent for eight violations of the Act and its implementing regulations within a forty-eight month period.

Complaint ¶ 1. CTP subsequently lowered the amount of civil money penalty it is seeking to \$7,500 "in light of Respondent's annual profits as well as other income that Respondent derives from tobacco sales." Informal Brief of Complainant at 9.

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 ENR Market has failed to comply with the Act and its implementing regulations. Respondent admitted to four violations for selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), three 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), and two violations for selling individual cigarettes, 21 C.F.R. § 1140.14(d). Each violation was committed by the owners of the establishment. 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 \$7,500 civil money penalty against Respondent ENR Market. Respondent states that the proposed penalty will cause "undue hardship because it will be difficult if not impossible to make it up." Informal Brief of Complainant at 9. Additionally, Respondent and his wife "can't physically work any more hours and they can't afford to hire anyone else." *Id.* Respondent provided no other evidence of its ability to pay, nor of the financial hardship that would be incurred if the penalty is imposed.

In its production of documents, Respondent ENR Market provided CTP with tax returns for 2012, 2013 and 2014. CTP states that Respondent reported an increasing Net Profit of over [REDACTED] each year, including [REDACTED] in income from [REDACTED] Tobacco sales each year.² In Respondent's lone tax return submitted into the record by CTP, for the year 2012, Respondent reported an annual profit of [REDACTED], with [REDACTED] Tobacco sales of [REDACTED]. CTP Exh. 1. Additionally, profits from the business were reported as Respondent's [REDACTED] income. Using these figures, imposition of a \$7,500 penalty would take away nearly [REDACTED] of Respondent's annual income, a severe punishment. Without Respondent's tax returns for 2013 and 2014, however, or any other evidence of Respondent's current financial situation, it is impossible to accurately assess Respondent's current ability to pay a civil money penalty.

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 ENR Market's ability to do business. Respondent did not address how this penalty will affect its ability to do business other than to state that it will be difficult to recover the lost profits and that it is now "emphatically clear" that it risks losing its business if it sells tobacco products to minors. Informal Brief of Complainant at 9. CTP argues that "[t]here is no evidence that this penalty will prevent Respondent from conducting the business," and "[t]he likely result will simply be lower profits for 2015." Informal Brief of Complainant at 10. Without evidence to the contrary, I must conclude that the proposed civil money penalty will not have a substantial effect on Respondent's ability to do business.

iv. History of Prior Violations

The current action is the third civil money penalty action brought against Respondent ENR Market within the past forty-eight months for violations of the Act and its implementing regulations. In the first civil money penalty action, CRD Docket Number C-13-1017, FDA Docket Number FDA-2013-H-0844, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on August 7, 2012, and January 29, 2013. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of

² In the Informal Brief of Complainant, CTP cites to Respondent's tax returns for the years 2012, 2013 and 2014 in CTP Exhibit 1. CTP Exhibit 1 only contains Respondent's tax returns for the year 2012, and omits Respondent's tax returns for the years 2013 and 2014. Therefore, CTP's claims regarding Respondent's tax returns for the years 2013 and 2014 are not supported by the evidentiary record.

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.

In the second civil money penalty action, CRD Docket Number C-14-870, FDA Docket Number FDA-2014-H-0378, Respondent ENR Market violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on October 21, 2013. On the same date, Respondent also violated the prohibition against selling individual cigarettes, 21 C.F.R. § 1140.14(d). An Initial Decision and Default Judgment issued, imposing a \$5,000 civil money penalty against Respondent.

The current action “brings Respondent’s total violation count to four sales to a minor in violation of 21 C.F.R. § 1140.14(a), three failures to verify identification in violation of 21 C.F.R. § 1140.14(b)(1), and two sales of individual cigarettes in violation of 21 C.F.R. § 1140.14(d).” Informal Brief of Complainant at 10. 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 substantial civil money penalties for its previous violations, its continued inability to comply with the federal tobacco regulations call for a more severe penalty.

v. Degree of Culpability

Respondent ENR Market admitted to all violations in its answer and informal brief. Both Respondent and his wife “acknowledge their misconduct and freely admit that they were wrong...” and “wish to apologize for their conduct...” Informal Brief of Respondent at 9. Based on Respondent ENR Market’s own admissions, I hold it fully culpable for all eight violations of the Act and its implementing regulations.

vi. Additional Mitigating Factors

Respondent ENR Market stated that it has taken steps to prevent future violations “by having age affidavits both in English and Spanish available to customers.” Informal Brief of Respondent at 9. Respondent also apologized for its conduct and “pledge[d] that it will not happen again.” *Id.*

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. However, CTP is accurate in its

assessment that “[i]n light of the multiple repeat violations, as well as Respondent’s unwillingness or inability to correct the violations, a large penalty is necessary in order for Respondent to grasp the seriousness and importance of these regulations.” *Id.* at 9. Based on the foregoing reasoning, I find CTP’s reduced penalty amount of \$7,500 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 **\$7,500** against Respondent, Vicente Cruz d/b/a ENR Market, for eight 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 forty-eight month period.

/s/

Catherine Ravinski
Administrative Law Judge