

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

CK Smoke Shop, LLC,

Respondent.

Docket No. C-15-2502
FDA No. FDA-2015-H-1711

Decision No. CR4513

Date: January 28, 2016

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, CK Smoke Shop, LLC for four 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 twenty-four month period. Specifically, CTP alleges that CK Smoke Shop, LLC violated the Act by impermissibly selling tobacco products 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 using a self-service display in a non-exempt facility.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$2,000 civil money penalty on Respondent CK Smoke Shop, LLC 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. In its

answer, Respondent admitted to all of the allegations, but asserted that the civil money penalty was too high. On July 1, 2015, I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges.

On July 31, 2015, CTP filed a Notice of Entry of Appearance, a Joint Status Report, and a Notice of Pending Settlement and Unopposed Motion to Extend Deadlines. The Notice of Pending Settlement and Unopposed Motion to Extend Deadlines stated that the parties had agreed to settle and that CTP understands that payment will be forthcoming. CTP requested that any deadlines, including the deadline to request documents, be extended by 30 days. On August 4, 2015, I extended the deadline for the parties to serve their requests for documents, and the parties' pre-hearing exchange deadlines.

CTP timely filed its pre-hearing exchange on October 21, 2015. Respondent's pre-hearing exchange was due on November 12, 2015, and to date Respondent has not filed a pre-hearing exchange.

As I had earlier been given notice of a pending settlement, on January 6, 2016, I ordered the parties to inform me whether they had reached a settlement. On January 19, 2016, CTP filed a Status Report that stated in pertinent part: "The parties reached a settlement agreement in this case; however, Respondent has failed to provide payment. In light of Respondent's failure to pay, as well as its failure to file a pre-hearing exchange, CTP intends to file a motion for sanctions and default judgment."

CTP's Intent to File a Motion for Sanctions

CTP has expressed an intent to file a motion for sanctions and default judgment because of Respondent's failure to provide the payment it agreed to as part of the settlement agreement, and because Respondent failed to file a pre-hearing exchange. I have no authority to enforce settlement agreements, and so I will not issue a default judgment because CTP asserts that Respondent failed to fulfill the terms of a settlement agreement. And, here, Respondent's failure to file a pre-hearing exchange is insufficient justification to issue a default judgment.

Decision on the Record

Pursuant to 21 C.F.R. § 17.37(b), all direct testimony of witnesses shall be admitted in the form of a written declaration. In its pre-hearing exchange, CTP did not submit any witness declarations. Respondent CK Smoke Shop, LLC has not submitted direct testimony. Because neither party has submitted any direct

testimony, there is no one to request to cross-examine. Therefore, I will decide this case on the basis of the written record.

Analysis

I. Violations

In its Complaint, CTP alleges that Respondent CK Smoke Shop, LLC committed four violations of the Act and its implementing regulations within a twenty-four month period. CK Smoke Shop, LLC filed an answer to the Complaint that admitted to all of the allegations, but asserted that the civil money penalty was too high. Answer.

CTP makes the following uncontested allegations:

- Respondent owns CK Smoke Shop, LLC, an establishment that sells tobacco products and is located at 457 West Washington Street, Sequim, Washington 98382. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on January 25, 2014, at approximately 2:39 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]” The inspector also observed that “the minor’s identification was not verified before the sale” Complaint ¶ 10.
- On May 8, 2014, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from January 25, 2014. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- UPS records show that the Warning Letter was received on May 9, 2014, but FDA did not receive a response. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on January 9, 2015, at approximately 1:19 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Top Regular Premium cigarette tobacco . . . [.]” The inspectors also documented that “the minor’s identification was not verified before the sale” Finally, an “inspector observed an unlocked

customer-accessible display containing Nat Sherman brand cigarettes and the most responsible person on duty told the inspector that small children are allowed to enter the establishment when accompanied by a parent.”
Complaint ¶ 1.

Respondent CK Smoke Shop, LLC does not dispute these allegations. Therefore, I find that these facts establish Respondent CK Smoke Shop, LLC’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 tobacco products 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 tobacco purchasers are younger than 18 years of age. Pursuant to 21 C.F.R. § 1140.16(c), self-service displays in facilities are prohibited where, at any time, persons younger than 18 years of age are present or permitted to enter.

Taking the above alleged facts as true, Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on January 25, 2014 and January 9, 2015. 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 tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). On January 9, 2015 and/or January 15, 2015, Respondent violated the prohibition against using a self-service display in a facility where minors were permitted to enter, 21 C.F.R. § 1140.16(c). Complaint ¶ 1; Informal Brief of Complainant, at 4. Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent CK Smoke Shop, LLC 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, \$2,000, against Respondent for four violations of the Act and its implementing regulations within a twenty-four period. Complaint ¶ 13. In its Informal Brief, CTP lowered the amount of the civil money penalty it was seeking to \$600. Informal Brief of Complainant at 5.

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 CK Smoke Shop, LLC has failed to comply with the Act and its implementing regulations. Respondent has admitted to all five violations discussed in the Complaint¹; specifically Respondent has admitted to: two violations of selling tobacco products to minors, two violations of failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and one violation of using a self-service display in a non-exempt facility. 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 \$600 civil money penalty against Respondent CK Smoke Shop, LLC. CTP asserts that Respondent did not argue that it was unable to pay the \$600 civil money penalty. In its Answer, Respondent asserted that the \$2,000 civil money penalty was too high because “[a]long with the increase of tobacco prices the economic recession my business is in financial difficulty. Even my sales tax is a month behind.” Respondent also requested a monthly payment plan. Respondent did not make any filings following the filing of CTP’s pre-hearing exchange that lowered the amount of the civil money penalty it was seeking to \$600.

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 CK Smoke Shop, LLC’s ability to do business. CTP asserts that “Respondent may continue to sell tobacco products and other products at the establishment.” Informal Brief of Complainant at 7. In asserting that a \$2,000 civil money penalty was too high, Respondent stated that he was a month behind in his sales tax. However, Respondent did not make any assertions as to whether a \$600 civil money penalty would have an effect on its ability to do business. Neither party has provided evidence of whether a \$600 civil money

¹ I note that CTP’s requested civil money penalty that was set forth in the Complaint is based upon 4 violations.

penalty against Respondent would have a substantial effect on Respondent's ability to do business.

iv. History of Prior Violations

The current action is the first civil money penalty action brought against Respondent CK Smoke Shop, LLC for violations of the Act and its implementing regulations. In this civil money penalty action, Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), 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), and used a self-service display in a facility where minors were permitted to enter, 21 C.F.R. § 1140.16(c).

I agree with CTP that "[t]hese repeat violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations." Informal Brief of Complainant at 7.

v. Degree of Culpability

Respondent CK Smoke Shop, LLC admitted to all violations. Based on Respondent CK Smoke Shop, LLC's own admissions, I hold it fully culpable for all five violations of the Act and its implementing regulations.²

vi. Additional Mitigating Factors

In its Answer, Respondent CK Smoke Shop, LLC stated that:

When I train my employees I always emphasize them to check the customer's ID and to ask the minors who are under 18 to leave the store. If customers are under 18 or do not possess any ID we ask them to leave. When families bring along their children under 12 they are asked to leave their children at the door to wait while they purchase products. I strictly train my employees to check the customer's ID always.

...

² I note that CTP's requested civil money penalty that was set forth in the Complaint is based upon four violations.

The last 14 years of my business the [only] time I received a compliance check premises check from the W.A. Liquor Control Board. I passed the check and received certificates. I promise to train my employees to check customers' ID thoroughly. Please consider this and I request for some leniency.

Answer.

vii. Penalty

I note that the record lacks evidence of Respondent's ability to pay a \$600 civil money penalty, and that the record does not contain evidence that shows the effect that a \$600 civil money penalty would have on Respondent's ability to do business. Respondent's request to lower the amount of the civil money penalty and mention of its financial difficulties were raised in response to a \$2,000 civil money penalty. Respondent did not file a response to CTP's pre-hearing exchange that lowered its requested civil money penalty to \$600. Respondent has not argued that he does not have the ability to pay a \$600 civil money penalty, nor does Respondent argue that such a penalty would affect his ability to do business. I acknowledge the Respondent's statements that he provides his employees with training and that he passed a prior compliance check. However, based on the foregoing reasoning, I find a penalty amount of \$600 to be appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

I also note Respondent's request for a monthly payment plan. I have no authority to address this request. My authority in this case is limited to deciding whether Respondent has violated applicable regulations and whether a civil money penalty amount is a reasonable remedy for any violation that is established.

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$600 against Respondent, CK Smoke Shop, LLC, for four 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 twenty-four month period.

/s/
Steven T. Kessel
Administrative Law Judge