

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,
(FDA No. FDA-2015-H-3268)

Complainant

v.

Pearl S and G, Inc.
d/b/a Pearl S and G / Smoke and Gifts,

Respondent.

Docket No. C-15-4036

Decision No. CR4813

Date: March 27, 2017

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty of \$11,000 against Respondent, Pearl S and G, Inc. d/b/a Pearl S and G / Smoke and Gifts, located at 8806 Pacific Avenue, Suite A, Tacoma, Washington 98444, for seven 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.

CTP alleges that Pearl S and G / Smoke and Gifts 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; selling adulterated (flavored) tobacco products; offering individual cigarettes for sale; and providing tobacco products for sale via self-service display in a non-exempted facility.

For the reasons discussed below, I impose a civil money penalty of \$9,000 against Respondent, Pearl S and G / Smoke and Gifts.

I. Procedural History

CTP began this matter by serving an administrative complaint seeking an \$11,000 civil money penalty on Respondent Pearl S and G / Smoke and Gifts (Respondent), at 8806 Pacific Avenue, Suite A, Tacoma, Washington 98444, 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. On October 28, 2015, Administrative Law Judge Steven T. Kessel issued an Acknowledgment and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges.

On January 7, 2016, CTP filed a Motion to Compel Discovery and a Motion to Extend Deadlines. In a January 12, 2016 letter issued at Judge Ravinski's direction, Respondent was given until January 22, 2016 to respond to CTP's motion. On January 12, 2016, Judge Ravinski also issued an Order extending the parties' exchange deadlines. CTP filed its pre-hearing exchange on February 18, 2016. Subsequently, Respondent timely filed its pre-hearing exchange, admitting all allegations in the Complaint but contesting the amount of the civil money penalty. On April 18, 2016, CTP filed a status report withdrawing its Motion to Compel Discovery. On July 18, 2016, this case was transferred to me.

II. A Decision on the Record Is Appropriate

Pursuant to 21 CFR § 17.37(b), all direct testimony of witnesses shall be admitted in the form of a written declaration. In their pre-hearing exchanges, neither CTP nor Respondent proposed any witnesses. Because Respondent has admitted all the allegations in the Complaint and there are no witness declarations, I will decide this case on the basis of the written record.

III. Discussion

A. Respondent has committed seven violations of the Act within a 48-month period.

In its Complaint, CTP alleges that Respondent committed seven¹ violations of the Act and its implementing regulations within a 48-month period.

¹ CTP's Complaint asserts that Respondent committed seven violations within a 48-month period, *see* Complaint ¶ 15, while its Informal Brief asserts that Respondent committed eight violations within a 48-month period. *See* Informal Brief of Complainant at 11. This decision relies on the number of allegations

On March 8, 2016, Respondent admitted the allegations in the Complaint, but contested the amount of the civil money penalty. Informal Brief of Respondent ¶¶ 4-8. The allegations to which Respondent admitted are as follows:

- CTP previously issued a warning letter to Respondent on April 25, 2013, citing two violations of 21 C.F.R. pt. 1140 on February 12, 2013, at Respondent’s business establishment, 8806 Pacific Avenue, Suite A, Tacoma, Washington 98444; Complaint ¶ 12, June 9, 2014 Complaint ¶ 11.
- On June 9, 2014, CTP initiated the first civil money penalty action, CRD Docket Number C-14-1281, FDA Docket Number FDA-2014-H-0777, against Respondent for receiving and proffering for delivery adulterated (flavored) tobacco products in violation of 21 U.S.C. § 331(c). CTP alleged this violation to have occurred on July 26, 2013. Complaint ¶ 11.
- The previous action concluded when Kelly Ko, Respondent’s authorized representative, settled the claims on Respondent’s behalf. On July 14, 2014, Ms. Ko signed an Acknowledgment Form in which she “admitt[ed] that the violations . . . occurred, waiv[ed] her ability to contest the violations in the future, and stat[ed] that she understood that violations may be counted in determining the total number of violations for purposes of future enforcement actions.” Complaint ¶ 13, January 5, 2015 Complaint ¶ 10.
- On January 9, 2015, CTP initiated the second civil money penalty action, CRD Docket Number C-15-830, FDA Docket Number FDA-2015-H-0036, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred on July 26, 2013 and September 19, 2014. Complaint ¶¶ 10, 11.
- The previous civil money penalty action concluded when Kelly Ko, Respondent’s authorized representative, settled the action with CTP on Respondent’s behalf. Ms. Ko signed an Acknowledgment Form, dated February 24, 2015 in which she “admitt[ed] that the violations . . . occurred, waiv[ed] her ability to contest the violations in the future, and stat[ed] that

levied in CTP’s Complaint, and not subsequent corrections. However, I note that either number of violations results in the same maximum penalty amount and the same statutory and regulatory analysis.

she understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions.”
Complaint ¶ 13.

- At approximately 2:19 p.m. on March 26, 2015, at Respondent’s business establishment, 8806 Pacific Avenue, Suite A, Tacoma, Washington 98444, FDA-commissioned inspectors documented that a person younger than 18 years of age was able to purchase an individual Newport cigarette. 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. Additionally, on April 1, 2015, an FDA-commissioned inspector observed TOP Make-Your-Own Cigarette Starter Kits containing cigarette tobacco on a shelf located on the main sales floor. Complaint ¶ 1.

Because Respondent has admitted to these allegations, I therefore find they establish Respondent’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).

Pursuant to 21 U.S.C. § 331(c), no retailer should receive the delivery or proffered delivery in interstate commerce of any tobacco product that is adulterated. 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. Pursuant to 21 C.F.R. § 1140.14(d), no retailer may open a cigarette package to sell individual cigarettes. In addition, the regulations prohibit the use of self-service displays in non-exempt facilities. 21 C.F.R. § 1140.16(c).

B. Imposition of a \$9,000 Civil Money Penalty Is Appropriate.

Pursuant to 21 U.S.C. § 333(f)(9), Respondent 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 of \$11,000 against Respondent for seven violations of the Act and its implementing regulations within a forty-eight month period. Complaint ¶¶ 1,

14, 15. In its Informal Brief, CTP asserts that an \$11,000 civil money penalty, the maximum allowable, is appropriate. Informal Brief of Complainant at 10.²

Respondent asserts that “[she] is financially unable to pay the fine.” Respondent further states that she has “been a single mom for over three years” and is raising children without child support since her divorce. Informal Brief of Respondent at 10. Additionally, Respondent states that “[t]he warnings and the first violation were given to my ex-husband and I was not aware to correct them. So I ended up violating the same mistakes which could have well been corrected with the warning.” *Id.*

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. § 333(f)(5)(B).

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

Respondent has consistently failed to comply with the Act and its implementing regulations. Respondent previously admitted to one violation for receiving and proffering for delivery adulterated (flavored) tobacco products in violation of 21 U.S.C. § 331(c), one violation for selling individual cigarettes, 21 C.F.R. § 1140.14(d), and one violation for using a self-service display in a non-exempt facility, 21 C.F.R. § 1140.16(c).

Presently, Respondent admits to four additional violations: one violation for selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a); one violation 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); one violation for selling individual cigarettes, 21 C.F.R. § 1140.14(d); and one violation for using a self-service display in a non-exempt facility, 21 C.F.R. § 1140.16(c), bringing the total to seven violations.

I must take into account Respondent’s ongoing failure to comply with federal tobacco regulations. Respondent’s principal, Ms. Ko, argues for reduced liability in part because of a change in management from her ex-husband to herself

² The citations to Complainant’s Informal Brief refer to Docket Entry #19, uploaded on January 4, 2017. Because Respondent’s tax returns in Complainant’s Informal Brief are neither identified as an exhibit or attachment nor paginated, the references to Complainant’s brief in this decision refer to the numbering from the Adobe pagination of the document, which was uploaded as a “PDF.”

in September 2014. Informal Brief of Respondent at 10. She further asserts notice of the first violation and warning were given to her ex-husband, of which she was ignorant, resulting in her committing similar errors. *Id.* But she concedes she had started the business with her ex-husband ten years earlier, and thus cannot credibly claim complete ignorance of the nature of her business, nor the limitations that routinely accompany the sales of tobacco products. *Id.*

Moreover, Ms. Ko was the authorized representative of Respondent who settled the 2013 violations in July 2014, and again settled the January 2015 action brought by CTP for violations that occurred 2013 and 2014. *See* Complaint ¶ 13. And, in March 2016, Ms. Ko again conceded allegations brought by CTP concerning two additional violations in 2015. Informal Brief of Respondent ¶¶ 4-8. As CTP notes, these latter violations are particularly noteworthy because they represent the second time Respondent had sold cigarettes to a minor, offered individual cigarettes for sale, and offered a self-service display. Informal Brief of Complainant at 10-11.

Ms. Ko's claim that she did not have sufficient warning about prior violations is thus without merit, as is her claim that Respondent be excused for her ignorance of the regulations. No merchant who conducts sales of tobacco products can plead ignorance of the regulations, and certainly not for repeated instances of failing to do so. The regulations governing the sale of tobacco products are set forth to protect public health, in particular the health of minors. The repeated violations to which Respondent admits are therefore quite serious in nature, and demand a proportional civil money penalty amount.

2. Respondent's Ability to Pay and Effect of the Penalty on Ability to do Business

I must also give consideration to Respondent's ability to pay and the effect of the civil money penalty on its ability to do business. 21 U.S.C. § 333(f)(5)(B). CTP seeks an \$11,000 civil money penalty against Respondent, which is also the maximum amount permissible under the regulations in effect during the relevant time period. Informal Brief of Complainant at 10. CTP states in its Informal Brief that in response to its Request for Production of Documents, Respondent provided tax returns from 2013 and 2014, which it attached to its Informal Brief. *Id.* at 17-18. Respondent has not provided additional tax return information for recent years, nor has it provided any other information I could use to assess its ability to pay or the effect of the penalty on its business. I therefore make my assessment of these statutory factors on the basis of these documents.

According to the 2013 and 2014 tax returns, Respondent reported [REDACTED]

[REDACTED]

In short, based on these figures, it appears Respondent has the ability to pay the \$11,000 penalty requested by CTP.

Beyond these tax documents, there is nothing in the evidentiary record that shows the effect an \$11,000 civil money penalty would have on Respondent's ability to do business. CTP asserts that "Respondent may continue to sell tobacco products and other products at the establishment. The likely result will simply be lower profits for 2016." Informal Brief of Complainant at 13. [REDACTED]

[REDACTED]

It appears that a civil money penalty of this amount would therefore have a significant effect on Respondent's ability to do business.

Finally, I note that Respondent's principal, Ms. Ko, argues that she is financially unable to pay the penalty because she is a recently divorced single mother who is currently without benefit of child support. Informal Brief of Respondent at 10. Ms. Ko has my full sympathies, but the question I must decide is whether Respondent, not Ms. Ko personally, is able to pay the penalty. I recognize that small businesses and their owners are often financially indistinguishable, but in this case, based on the discussion above, Respondent has the means to pay a civil money penalty without affecting the salary paid to Ms. Ko as an officer.

3. History of Prior Violations

The current action is the third civil money penalty action brought against Respondent for violations of the Act and its implementing regulations. The current action brings Respondent's total violation count to seven violations in a 48-month period. Informal Brief of Complainant at 13. 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 civil money penalties for its previous violations, its continued inability or unwillingness to comply with federal tobacco laws and regulations militates towards a more severe penalty.

4. Degree of Culpability

Respondent admitted to all violations in its informal brief. Based on Respondent's own admissions, it is fully culpable for all seven violations of the Act and its implementing regulations.

5. Penalty

I acknowledge the financial strain the full penalty amount will have on Respondent's small business, particularly in light of its principals' personal issues. I have also considered the other statutory factors, which militate against reducing the penalty amount. In particular, Respondent has a history of repeated violations of tobacco regulations. Early attempts at intervention and warnings from CTP did not affect Respondent's behavior. Neither did subsequent civil actions or even progressively larger civil money penalties. However, at least one statutory factor suggests a somewhat lower penalty amount would be sufficient. And, Respondent has specified steps it has taken in an effort to come into compliance, including additional training measures and tighter enforcement. Respondent's Informal Brief at 5. For these reasons, after considering all the statutory factors, and in light of the administrative record before me, I find a civil money penalty amount of \$9,000 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

ORDER

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$9,000 against Respondent, Pearl S and G, Inc. d/b/a Pearl S and G / Smoke and Gifts, for seven 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/
Bill Thomas
Administrative Law Judge