

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-1414)

Complainant

v.

Will Corp, Inc.
d/b/a Macadoodles,

Respondent.

Docket No. C-15-2241

Decision No. CR4490

Date: December 16, 2015

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Will Corp, Inc. d/b/a Macadoodles, located at 3105 East 17th Street, Joplin, Missouri 64804, 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 Macadoodles 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, using a self-service display in a non-exempt facility and failing to ensure that self-service displays, advertising, labeling, etc. that do not comply with the requirements are brought into compliance.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$5,000 civil money penalty on Respondent Macadoodles, at 3105 East 17th Street, Joplin, Missouri 64804, 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 admitted to selling to a minor, but contested the calculation of the number of violations and the amount of the civil money penalty. On June 26, 2015, I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges. On June 30, 2015, I issued an amended APHO. Respondent filed its pre-hearing exchange on July 15, 2015. In its pre-hearing exchange, Respondent again admitted to selling to a minor, but contested the calculation of the number of violations and the amount of the civil money penalty. CTP filed its pre-hearing exchange on September 18, 2015. On December 10, 2015, I held a pre-hearing conference in this case.

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 submitted two witness declarations. Respondent Macadoodles has not submitted direct testimony. During the pre-hearing conference held on December 10, 2015, Respondent indicated that it did not wish to cross examine CTP's witnesses. Because Respondent Macadoodles has not submitted any direct testimony, there is no one for CTP to request to cross-examine. And, since Respondent Macadoodles has admitted to the allegation of selling to a minor, 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 Macadoodles committed five violations of the Act and its implementing regulations within a thirty-six month period. Macadoodles filed an answer to the Complaint that admitted to selling to a minor, but contested the calculation of the number of violations and the amount of the civil money penalty. Answer. Additionally, on July 15, 2015, Macadoodles filed an informal brief that again admitted to selling to a minor, but contested the calculation of the number of violations and the amount of the civil money penalty. Informal Brief of Respondent.

The Complaint currently before me involves two prior complaints. Both prior complaints were settled by the parties and in both prior complaints the Respondent's representative admitted the violations occurred, waived the 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 future enforcement actions. Complaint; Informal Brief of Complainant. The Complaint currently before me only involves one new violation, impermissibly selling cigarettes to a minor, which Respondent has admitted. Therefore, Respondent Macadoodles has admitted to all violations in the current Complaint.

CTP makes the following uncontested allegations:

- CTP previously issued a warning letter to Respondent Macadoodles on March 8, 2012, citing violations of 21 C.F.R. pt. 1140 on January 31, 2012, at Respondent's business establishment, 3105 East 17th Street, Joplin, Missouri 64804;
- On January 8, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-229, FDA Docket Number FDA-2012-H-1249, against Respondent Macadoodles for two violations of 21 C.F.R. pt. 1140 within a 12-month period. CTP alleged those violations to have occurred on January 31, 2012, and June 26, 2012;
- The previous civil money penalty action docketed C-13-229 concluded when Respondent's authorized representative settled the action with CTP on Respondent's behalf. Respondent's representative signed an Acknowledgment Form, dated February 26, 2013, in which he admitted to the violations;
- On December 2, 2013, CTP initiated a second civil money penalty action, CRD Docket Number C-14-262, FDA Docket Number FDA-2013-H-1455, against Respondent for four violations of 21 C.F.R. pt. 1140 within a 24-month period. Specifically, those violations included two violations on May 31, 2013, when Respondent sold tobacco products to a minor and failed to verify, by means of photographic identification, that the tobacco purchaser was 18 years of age or older; and two violations from the civil money penalty action docketed as C-13-229;
- The second civil money penalty action concluded when Larry E. Williams, Respondent's authorized representative, settled the claims on Respondent's behalf. Mr. Williams signed an Acknowledgment Form dated February 13, 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 February 21, 2014;

- During a subsequent two-part inspection of Respondent’s business establishment, 3105 East 17th Street, Joplin, Missouri 64804, at approximately 1:24 p.m. on November 21, 2014, FDA-commissioned inspectors documented Respondent’s staff selling a package of Pall Mall cigarettes to a person younger than 18 years of age.

Complaint; Informal Brief of Complainant.

Respondent Macadoodles does not dispute these allegations. Therefore, I find that these facts establish Respondent Will Corp, Inc. d/b/a Macadoodles’ 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 are prohibited in facilities where, at any time, persons younger than 18 years of age are present or permitted to enter. Finally, under 21 C.F.R. § 1140.14(e), retailers must ensure that self-service displays, advertising, labeling, etc. that do not comply with the requirements are removed or made to comply with the requirements.

A. II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Macadoodles 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 ¶ 15. In its Informal Brief, CTP continues to assert that a \$5,000 civil money penalty is appropriate. Informal Brief of Complainant at 6.

Respondent Macadoodles argues that:

As we are aware there are 5 allegations . . . 3 of which are related to product misplacement. The product misplacement violations have since been resolved and were found to be concurrent before [Macadoodles] received the first warning. As we were unaware of the first violation/warning before a second and then third were issued we contest this violation as a single occurrence. After considering this as a single occurrence, there are only a total of 3 violations by Macadoodles. This would reduce the penalty from \$5,000 to \$500.”

Informal Brief of Respondent. Essentially Respondent is arguing that CTP should charge only one violation for all three of the violations involving “product misplacement”.

In its Informal Brief, CTP states that:

FDA counts only one violation from the first inspection of a tobacco retailer that finds one or more violations of FDA regulations, regardless of the number of violations that were noted and included in a Warning Letter. For any subsequent inspections, FDA may count any or all violations and its general policy is to count all of them individually.

Informal Brief of Complainant at 7. First, I note that CTP’s practice of charging more than one violation per inspection is not inconsistent with the regulations. Two violations involving “product misplacement” were cited on January 31, 2012, but CTP only counted one of those violations when calculating the civil money penalty. One violation involving a self-service display was cited on June 26, 2012. Despite Respondent Macadoodles’ argument, CTP is not required to consider all violations involving “product misplacement” to be one violation.

Finally, I note that Respondent asserts that it was not aware of the first “product misplacement” violation before the second or the third violation was issued; however, Respondent has provided no evidence of this assertion. Further, the first two “product misplacement” violations occurred on the same date, and Respondent was only penalized for one of those violations. Therefore, Respondent was only penalized for 2 of the 3 “product misplacement” violations. Finally, Respondent Macadoodles settled the complaint involving those three violations. Respondent had the opportunity to raise the issue regarding fairness of notification and computation of the penalty involving those three “product

misplacement” violations when settling that complaint. Presumably Respondent was satisfied with the settlement, as he agreed to it.

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 Macadoodles has failed to comply with the Act and its implementing regulations. Over the course of the six violations discussed in this Complaint, Respondent has admitted to all six violations¹; specifically Respondent has admitted to: two violations for selling tobacco products to minors, one violation for failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, two violations for using a self-service display in a non-exempt facility and one violation for failing to ensure that self-service displays, advertising, labeling, etc. that do not comply with the requirements are brought into compliance. 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 Macadoodles. In its production of documents, Respondent Macadoodles provided CTP with one quarterly tax return for 2013, one quarterly tax return for 2014 and a document entitled “Department Net Sales, Margin and Volume Report” that covered a period of January 1, 2012, through August 26, 2015. CTP asserts that based on Respondent’s net sales reported in the document entitled “Department Net Sales, Margin and Volume Report” that Respondent has the ability to pay the \$5,000 civil money penalty.

Respondent Macadoodles states that since the business opened on December 19, 2008, it has sold a total of 212,673 tobacco products. Respondent further asserts that “[i]f the maximum alleged penalty is imposed, it would put a dire hardship on our ability to continue selling tobacco products, generating revenue, and paying appropriate taxes.”

¹ I note that CTP’s requested civil money penalty is based upon 5 violations.

While the quarterly tax returns show only brief snap shots in time, it appears that the Respondent has the ability to pay a \$5,000 penalty. Respondent has not provided evidence to show that it would be unable to pay a \$5,000 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 Macadoodles' ability to do business. CTP asserts that considering the total net sales, a \$5,000 penalty should not prevent Respondent from conducting business. CTP states that the likely result of the \$5,000 penalty may simply be lower profits for 2015. Informal Brief of Complainant at 10. Respondent stated that this penalty would cause it to have to make a determination as to whether it would continue to sell cigarettes. Informal Brief of Respondent. While the penalty may cause respondent to consider whether it would continue to sell cigarettes, I have not been provided evidence that would indicate that fact. 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 would 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 Macadoodles since January 8, 2013 for violations of the Act and its implementing regulations. In the first civil money penalty action, CRD Docket Number C-13-229, FDA Docket Number FDA-2012-H-1249, Respondent violated the prohibition against using a self-service display in a non-exempt facility, 21 C.F.R. § 1140.16(c), on January 31, 2012, and June 26, 2012, and failed to ensure that self-service displays, advertising, labeling, etc. that did not comply with the requirements were brought into compliance, 21 C.F.R. § 1140.14(e), on January 31, 2012. In the second civil money penalty action, CRD Docket Number C-14-262, FDA Docket Number FDA-2013-H-1455, on May 31, 2013, Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and 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). Respondent settled both of the prior complaints with CTP for an undisclosed penalty amount.

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 Macadoodles admitted to all violations. Based on Respondent Macadoodles' own admissions, I hold it fully culpable for all six violations of the Act and its implementing regulations.²

vi. Additional Mitigating Factors

Respondent Macadoodles stated that in response to each notification it "has reviewed, revised, and retained our staff to ensure compliance." Further, Respondent states that it had management and employees sign and date the packet that "Alcohol and Tobacco control" sent to the store, and that the packet is placed in the employee's folder. Finally, Respondent states that the employee that made both sales to a minor no longer works for Respondent. Informal Brief of Respondent.

vii. Penalty

I acknowledge the steps taken by Respondent to ensure additional future violations are not found. However, based on the foregoing reasoning, I find a penalty amount of \$5,000 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 \$5,000 against Respondent, Will Corp, Inc. d/b/a Macadoodles, 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

² I note that CTP's requested civil money penalty is based upon 5 violations.