

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

Center for Tobacco Products,
Complainant,

v.

F. Rahaman Corporation
d/b/a Desi Food Mart,
Respondent.

CRD Docket No. T-18-1750
FDA Docket No. FDA-2018-H-1268

Decision No. TB3273

Date: November 21, 2018

DECISION

Found:

1. Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i), on March 10, 2018, as charged in the Complaint; and
2. Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i),¹ as charged in prior complaints; and
3. Respondent committed seven violations in a 48-month period as set forth hereinabove; and
4. Respondent is hereby assessed a civil money penalty in the amount of \$3,000.

Glossary:

ALJ	administrative law judge ²
CMP	civil money penalty
CTP/Complainant	Center for Tobacco Products
FDCA	Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9)

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

² See 5 C.F.R. § 930.204.

FDA Food and Drug Administration
HHS Department of Health and Human Services
Respondent F. Rahaman Corporation d/b/a Desi Food Mart
TCA The Family Smoking Prevention and Tobacco Control Act,
Pub. L. No. 111-31, 123 Stat. 1776 (2009)

I. JURISDICTION

I have jurisdiction to hear this case pursuant to my appointment by the Secretary of Health and Human Services and my authority under the Administrative Procedure Act (5 U.S.C. §§ 554-556), 5 U.S.C.A. § 3106, 21 U.S.C. § 333(f)(5), 5 C.F.R. §§ 930.201 *et seq.* and 21 C.F.R. Part 17.³

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (Complainant or CTP) filed a Complaint dated March 26, 2018, against F. Rahaman Corporation d/b/a Desi Food Mart (Respondent or Desi Food Mart), alleging that FDA documented seven violations within a 48-month period. CTP seeks a civil money penalty (CMP) in the amount of \$11,182.

Respondent was served with process on March 28, 2018. On April 25, 2018, Respondent, through counsel, filed an Answer and requested a hearing.⁴ On April 27, 2018, I issued a Pre-Hearing Order setting a schedule for filings and procedures.

³ See also *Butz v. Economou*, 438 U.S. 478, 513 (1978); *Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980); *Fed. Maritime Com'n v. S.C. State Ports Auth.*, 535 U.S. 743, 744 (2002).

⁴ On April 16, 2018, Respondent filed a timely motion for extension requesting additional time to file an Answer. I granted Respondent's motion on April 23, 2018, allowing Respondent until May 29, 2018 to file its Answer.

On May 4, 2018, Respondent's counsel advised that Respondent would like to stipulate to the Complaint allegations and requested that a lower penalty be assessed. On May 18, 2018, CTP filed a Stipulation of Fact (Stipulation) signed by counsel of record for both parties. In the Stipulation, the parties agreed to the facts alleged in the Complaint. On May 21, 2018, Respondent filed a letter requesting a reduction of the CMP and submitted copies of Respondent's 2016 and 2017 tax returns.

On July 30, 2018, CTP filed its pre-hearing exchange, consisting of an informal brief and seven proposed exhibits (CTP Exs. 1-7), including the previously filed Stipulation (CTP Ex. 7). CTP proposed no witnesses. As of the deadline set in my Pre-Hearing Order, Respondent failed to file its pre-hearing exchange or propose any witnesses.

On August 16, 2018, both parties represented their intent to waive a hearing on the merits in this matter, but asked to submit briefs on the appropriateness of the penalty. Accordingly, on August 16, 2018, I issued an Order scheduling briefing on the appropriate penalty in this case.

Both parties filed their respective briefs and moved to admit their proposed exhibits into evidence for my consideration. Respondent moved to admit exhibits A-C attached to its Answer (DAB E-File Docket (Dkt.) No. 8, at 13-18; *see also* Dkt. No. 6b, at 1-5), Respondent's 2016 and 2017 tax returns (Dkt. No. 15, at 3-49), and its banking records (Dkt. No. 28, at 2-54). CTP objected to the admission of Respondent's banking records on the grounds that Respondent failed to produce the records in discovery or provide them in a pre-hearing exchange. CTP moved to admit eight exhibits (CTP Exs.

1-8). (Dkt. Nos. 18b-18h and 30a). Respondent did not object to the admission of CTP's exhibits into evidence.

This matter is now ready for decision. 21 C.F.R. § 17.45(c). I admit into evidence the parties' proposed exhibits, including the Stipulation, and decide this case based on the written record. 21 C.F.R. § 17.19(b)(11), (17).

III. BURDEN OF PROOF

As the petitioning party, CTP has the burden to prove, by a preponderance of the evidence, that Respondent is liable and that the proffered CMP is appropriate. 21 C.F.R. § 17.33.

IV. LAW

21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i).

V. ISSUES

- a. Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i), as alleged in the Complaint?
- b. If so, is a CMP in the amount of \$11,182 appropriate?

VI. COMPLAINT ALLEGATIONS

In its Complaint, CTP alleged that Respondent owns an establishment doing business under the name of Desi Food Mart, located at 714 Ashley Boulevard, New Bedford, Massachusetts 02745. CTP also alleged that Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

During an inspection of Desi Food Mart conducted on March 10, 2018, an FDA-commissioned inspector documented the following violations:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on March 10, 2018, at approximately 1:54 PM; and
- b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on March 10, 2018, at approximately 1:54 PM.

VII. PRIOR VIOLATIONS

On February 9, 2017, CTP initiated its first CMP action, CRD Docket Number T-17-1928, FDA Docket Number FDA-2017-H-0515, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged Respondent sold cigarettes to minors on April 12, 2016 and July 25, 2016, and failed to verify the age of a person purchasing cigarettes by means of photographic identification containing the bearer's date of birth on July 25, 2016. *See* CTP Ex. 1.

The first CMP action concluded when Respondent admitted the allegations contained in the complaint and paid the agreed upon monetary penalty in settlement of that claim. Further, Respondent expressly waived its right to contest such violations in subsequent actions. *See* CTP Ex. 2.

On November 22, 2017, CTP initiated a second CMP action, CRD Docket Number T-18-455, FDA Docket Number FDA-2017-H-6576, against Respondent for five⁵ violations of 21 C.F.R. pt. 1140 within a 36-month period. CTP alleged Respondent sold cigarettes to a minor and failed to verify the age of a person purchasing cigarettes by means of photographic identification containing the bearer's date of birth on November 3, 2017. *See* CTP Ex. 3.

The second CMP action concluded when Respondent admitted the allegations contained in the complaint and paid the agreed upon monetary penalty in settlement of that claim. Further, Respondent expressly waived its right to contest such violations in subsequent actions. *See* CTP Ex. 4.

VIII. STIPULATION

In the Stipulation admitted into evidence, the parties agreed to be bound to the following facts that gave rise to Respondent's violations:

- a. Respondent owns an establishment that does business under the name Desi Food Mart and is located at 714 Ashley Boulevard, New Bedford, Massachusetts 02745. CTP Ex. 7 ¶ 1.
- b. Respondent receives tobacco products in interstate commerce, including Newport Box 100s cigarettes, and holds them for sale. CTP Ex. 7 ¶ 2.

⁵ One violation was documented on April 12, 2016 (sale of cigarettes to a minor), two on July 25, 2016 (sale of cigarettes to a minor and failure to verify ID), and two on November 3, 2017 (sale of cigarettes to a minor and failure to verify ID). *See* CTP Exs. 1, 3.

- c. Respondent sold a package of Newport Box 100s cigarettes to a person younger than 18 years of age on March 10, 2018, at approximately 1:54 PM. CTP Ex. 7 ¶ 3. Respondent also failed to verify the age of the purchaser by means of photographic identification containing the bearer's date of birth during the sale on March 10, 2018, at approximately 1:54 PM. *Id.*
- d. On November 22, 2017, CTP initiated a previous CMP action alleging that Respondent sold cigarettes to a person younger than 18 years of age on April 12, 2016, July 25, 2016, and November 3, 2017, and failed to verify the age of a person purchasing cigarettes by means of photographic identification containing the bearer's date of birth on July 25, 2016 and November 3, 2017. CTP Ex. 7 ¶ 4. The previous CMP action was closed after Respondent admitted all allegations in the Complaint and paid the agreed upon penalty. *Id.*

IX. FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

The “relevant statute” in this case is actually a combination of statutes and regulations: The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (TCA), amended the Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) (FDCA) and created a new subchapter of the FDCA that dealt exclusively with tobacco products, (21 U.S.C. §§ 387-387u), and it also modified other parts of the FDCA explicitly to include tobacco products among the regulated products whose misbranding can give rise to civil, and in some cases criminal, liability. The 2009 amendments to the FDCA contained within the TCA also charged the Secretary of Health

and Human Services with, among other things, creating regulations to govern tobacco sales. The Secretary's regulations on tobacco products appear in Part 1140 of Title 21, Code of Federal Regulations.

Under the FDCA, “[a] tobacco product shall be deemed to be misbranded if, in the case of any tobacco product sold or offered for sale in any State, it is sold or distributed in violation of regulations prescribed under section 387f(d).” 21 U.S.C. § 387c(a)(7)(B) (2012). Section 387a-1 directed FDA to re-issue, with some modifications, regulations previously passed in 1996. 21 U.S.C. § 387a-1(a) (2012). These regulations were passed pursuant to section 387f(d), which authorizes FDA to promulgate regulations on the sale and distribution of tobacco products; 75 Fed. Reg. 13,225 (Mar. 19, 2010), codified at 21 C.F.R. Part 1140 (2015); 21 U.S.C. § 387f(d)(1) (2012). Accordingly, 21 C.F.R. § 1140.1(b) provides that “failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.”

Under 21 U.S.C. § 331(k), “[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded” is a prohibited act under 21 U.S.C. § 331. Thus, when a retailer such as Respondent misbrands a tobacco product by violating a requirement of 21 C.F.R. Part 1140, that misbranding in turn violates the FDCA, specifically 21 U.S.C. § 331(k). FDA may seek a CMP from “any

person who violates a requirement of this chapter which relates to tobacco products.” 21 U.S.C. § 333(f)(9)(A) (2012). Penalties are set by 21 U.S.C. § 333 note and 21 C.F.R. § 17.2.

Under current FDA policy, the first time FDA finds violations of 21 C.F.R. Part 1140 at an establishment, FDA only counts one violation regardless of the number of specific regulatory requirements that were actually violated, but if FDA finds violations on subsequent occasions, it will count violations of specific regulatory requirements individually in computing any CMP sought. This policy is set forth in detail, with examples to illustrate, at *U.S. Food & Drug Admin., Guidance for Industry and FDA Staff, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions (Revised)* (2016), available at <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf> [hereinafter *Guidance for Industry*], at 13-14. So, for instance, if a retailer sells a tobacco product on a particular occasion to a minor without checking for photographic identification, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i), this will count as two separate violations for purposes of computing the CMP, unless it is the first time violations were observed at that particular establishment. This policy of counting violations has been determined by the HHS Departmental Appeals Board to be consistent with the language of the FDCA and its implementing regulations. *See Orton Motor Co. d/b/a Orton's Bagley v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).

X. LIABILITY

When a retailer such as Respondent is found to have “misbranded” a tobacco product in interstate commerce, it can be liable to pay a CMP. 21 U.S.C. §§ 331, 333.

Based on the executed settlement agreements (CTP Exs. 2 and 4), Respondent previously admitted to five violations of 21 U.S.C. § 331, specifically three violations of 21 C.F.R. § 1140.14(a)(1) on April 12, 2016, July 25, 2016, and November 3, 2017, and two violations of 21 C.F.R. § 1140.14(a)(2)(i) on July 25, 2016, and November 3, 2017, as set forth in prior complaints. Thus, the prior five violations are administratively final.

Based on the Stipulation and evidence presented, I find and conclude that Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), in that a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on March 10, 2018, at approximately 1:54 PM.

I further find and conclude that, based on the Stipulation and evidence presented, Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i), on that same date, in that Respondent failed to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchaser is younger than 18 years of age.

The conduct on March 10, 2018 set forth above counts as two violations under the FDA policy for purposes of computing the CMP in the instant case. *See Guidance for Industry*, at 13-14. As discussed, Respondent previously admitted to five violations in the relevant timeframe.

Accordingly, I find and conclude that Respondent is liable for seven violations of the FDCA and its implementing regulations within a 48-month period.

XI. PENALTY

There being liability under the relevant statute, I must now determine the amount of penalty to impose. Pursuant to 21 U.S.C. § 333(f)(9), Respondent is liable for a CMP not to exceed the amounts listed in FDA's CMP regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the maximum penalty amount, \$11,182, against Respondent for seven violations of the FDCA and its implementing regulations within a 48-month period.

Respondent asked for a reduction of the CMP to \$1,000-\$1,500 arguing:

(1) Respondent had staffing issues due to its owner being out of the country for over a year until the beginning of July 2018; (2) Respondent makes very little profit from the sale of cigarettes; (3) Respondent's store was burglarized twice in 2018; and (4) Respondent cannot afford a large penalty because of its low income, high credit balance, and insufficient checking and savings account funds. Dkt. No. 26. In support of its arguments, Respondent submitted copies of: (1) its employee agreement requiring employees to check IDs of tobacco purchasers under the age of 27, (2) signs posted in the store prohibiting sales of tobacco products to anyone under 18 and requiring identification, (3) pictures of Respondent's burglarized store, (4) banking records, and (5) 2016 and 2017 tax returns. Dkt. Nos. 8, 15 and 28.

In its briefs, CTP continued to assert that an \$11,182 CMP is appropriate for seven violations within a 48-month period. Dkt. Nos. 18 and 30. CTP argues that Respondent

provided no written testimony to support the assertions of staffing issues or burglary reports. Dkt. No. 30, at 4. CTP also contends that Respondent provided no evidence of its gross profits from the sale of tobacco products month by month for 2018. *Id.* at 4-5. CTP argues that in the absence of sworn testimony or supporting documentation, this information cannot be considered when determining the appropriate amount of the CMP. *Id.* CTP maintains that Respondent's tax returns alone are insufficient to prove that Respondent is unable to pay the CMP. *Id.* at 7. According to CTP, in order to establish inability to pay, Respondent should have provided evidence of its business income and assets such as cash reserves or credit worthiness. *Id.* [REDACTED]

[REDACTED]

[REDACTED]

Since I found that Respondent is liable for seven violations of the FDCA and its implementing regulations within a 48-month period, the next step is to determine the amount of the CMP. When making that determination, 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).

a. The nature, circumstances, extent, and gravity of the violation

I have found that Respondent is liable for four violations of selling tobacco products to minors, and three violation for failure to verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers

are younger than 18 years of age, totaling seven violations of the tobacco regulations. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the CMP amount should be set accordingly.

b. Respondent's ability to pay and to do business

CTP is seeking an \$11,182 CMP against Respondent. Respondent contends that it lacks the financial wherewithal to pay a CMP of \$11,182. [REDACTED]

CTP asserts that an \$11,182 CMP will not affect Respondent's ability to do business, because "Respondent may continue to sell tobacco products and other products at the establishment." Dkt. No. 30, at 7. While the record does not include specific evidence to show the effects of an \$11,182 CMP, it appears that a CMP of this amount will have a substantial effect on Respondent's ability to do business. The purpose of the penalty, however, is to promote compliance and penalize for non-compliance, but not to put a company out of business.

c. History of prior violations

The current action is the third CMP action brought against Respondent since February 9, 2017 for violations of the FDCA and its implementing regulations. The first CMP action, CRD Docket Number T-17-1928, FDA Docket Number FDA-2017-H-0515, was brought against Respondent for two violations of 21 C.F.R. § 1140.14(a)(1) and one violation of 21 C.F.R. § 1140.14(a)(2)(i). *See* CTP Ex. 1. Respondent settled the first complaint on March 3, 2017. *See* CTP Ex. 2.

On November 22, 2017, CTP brought the second CMP action, CRD Docket Number T-18-455, FDA Docket Number FDA-2017-H-6576, against Respondent for two additional violations—one violation of 21 C.F.R. § 1140.14(a)(1) and one violation of 21 C.F.R. § 1140.14(a)(2)(i). *See* CTP Ex. 3. Respondent settled the second complaint on February 7, 2018, allegedly for \$1,500. *See* CTP Ex. 4; *see also* Dkt. No. 25, at 2. Yet, a little over a month later, on March 10, 2018, Respondent once again sold cigarettes to a minor and failed to verify the identification of the purchaser. Respondent has admitted to all these violations. *See* CTP Ex. 7.

I agree with CTP that “[t]hese repeated violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations.” Dkt. No. 30, at 8. While Respondent has already paid for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

d. Degree of culpability

Respondent admitted to five violations of the FDCA and its implementing regulations in the settlement agreements of the prior actions. In addition, based on the

Stipulation and evidence presented, I found Respondent committed the most recent violations in the current Complaint. Therefore, I hold Respondent fully culpable for seven violations of the FDCA and its implementing regulations.

e. Additional mitigating factors

Mitigation is an affirmative defense for which Respondent bears the burden of proof. 21 C.F.R. § 17.33(c). Respondent has taken responsibility for its actions by admitting the violations, but requested a penalty in the amount of \$1,000-\$1,500. Respondent claimed that it “simply cannot afford a large penalty” and stated that it has taken steps to prevent future violations. Dkt. No. 26, at 2-3. Specifically, Respondent states that: (1) employees who conducted the sales at issue were terminated (Dkt. No. 26, at 2); (2) Desi Food Mart “put up signs in the store prohibiting sales of cigarettes to minors (*Id.* at 2-3; *see also* Dkt. No. 8, at 14-15); and (3) Desi Food Mart “is now being run solely by [the owners] and they both constantly check IDs” (Dkt. No. 26, at 3).

f. Penalty

I acknowledge the financial strain a large penalty amount will have on Respondent’s small business and conclude a reduced penalty amount of \$3,000 is appropriate under 21 U.S.C. § 333(f)(5)(B) and (f)(9).

XII. CONCLUSION

Respondent committed seven violations of the FDCA and its implementing regulations within a 48-month period. Respondent is liable for a CMP of \$3,000. *See* 21 C.F.R. § 17.2.

WHEREFORE, evidence having been read and considered it be and is hereby

ORDERED as follows:

- a. I find Respondent was served with process herein and is subject to this forum;
- b. I find and conclude that the evidentiary facts support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i) on March 10, 2018, in that Respondent sold a package of Newport Box 100s cigarettes to a person younger than 18 years of age and failed to verify the age of the person purchasing cigarettes by means of photographic identification containing the bearer's date of birth, as set forth in the Complaint and admitted in the Stipulation of Fact;
- c. I find and conclude that the evidentiary facts support a finding Respondent: (1) violated 21 C.F.R. § 1140.14(a)(1) on April 12, 2016, July 25, 2016, and November 3, 2017, in that Respondent sold cigarettes to persons younger than 18 years of age; and (2) violated 21 C.F.R. § 1140.14(a)(2)(i) on July 25, 2016 and November 3, 2017, in that Respondent failed to verify the age of the persons purchasing cigarettes by means of photographic identification containing the bearer's date of birth, as stipulated in the settlement agreements of the prior actions;
- d. I find and conclude Respondent committed seven violations of the FDCA and its implementing regulations within a 48-month period; and
- e. I assess a monetary penalty in the amount of \$3,000.

_____/s/_____

Richard C. Goodwin
U.S. Administrative Law Judge