

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2015-H-1841)

Complainant

v.

Kuma H. Mamie  
d/b/a 7-Eleven Store 22921A<sup>1</sup>,

Respondent.

Docket No. C-15-2595

Decision No. CR4485

Date: December 8, 2015

**INITIAL DECISION**

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Kuma H. Mamie d/b/a 7-Eleven Store 22921A, located at 8101 Fenton Street, Silver Spring, Maryland 20910, for six 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 7-Eleven Store 22921A violated the Act by impermissibly selling cigarettes to minors, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older.

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<sup>1</sup> On October 8, 2015, CTP motioned for leave to amend the complaint to change the name of Respondent from Kuma H. Mamie d/b/a 7-Eleven 22921 to Kuma H. Mamie d/b/a 7-Eleven Store 22921A. On October 13, 2015, an order granting CTP's motion for leave to amend the complaint was granted.

## **Procedural History**

CTP began this matter by serving an administrative complaint seeking an \$11,000 civil money penalty on Respondent 7-Eleven Store 22921A, at 8101 Fenton Street, Silver Spring, Maryland 20910, 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 July 7, 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 October 28, 2015. Subsequently, Respondent 7-Eleven Store 22921A timely filed its pre-hearing exchange, admitting all allegations in the Complaint but contesting the amount of the civil money penalty.

## **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 pre-hearing exchange, CTP submitted two witness declarations. Respondent 7-Eleven Store 22921A submitted one witness declaration. Because Respondent 7-Eleven Store 22921A has admitted all the allegations in the Complaint, CTP's witness declarations 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 7-Eleven Store 22921A committed six violations of the Act and its implementing regulations within a forty-eight month period. On November 18, 2015, 7-Eleven Store 22921A filed an informal brief, admitting all the allegations in the Complaint, but contesting the amount of the civil money penalty. Informal Brief of Respondent ¶¶ 4,5,6.

CTP makes the following uncontested allegations:

- CTP previously issued a warning letter to Respondent 7-Eleven Store 22921A on October 11, 2012, citing a violation of 21 C.F.R. pt. 1140 on August 2, 2012, at Respondent's business establishment, 8101 Fenton Street, Silver Spring, Maryland 20910;
- On July 9, 2013, CTP initiated the first civil money penalty action, CRD Docket Number C-13-973, FDA Docket Number FDA-2013-H-0809, against Respondent 7-Eleven Store 22921A for three violations of

21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred on August 2, 2012, and December 13, 2012;

- The previous action concluded when an Initial Decision and Default Judgment was entered by an Administrative Law Judge on September 26, 2013, “which found Respondent liable under the Act for the violations as alleged ....” The Initial Decision and Default Judgment became final and binding on the parties on October 26, 2013;
- On July 16, 2014, CTP initiated the second civil money penalty action, CRD Docket Number C-14-1400, FDA Docket Number FDA-2014-H-0904, against Respondent 7-Eleven Store 22921A for four violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred on August 2, 2012, December 13, 2012, and November 19, 2013;
- The previous civil money penalty action concluded when Kuma Mamie, Respondent’s authorized representative, settled the action with CTP on Respondent’s behalf. Mr. Mamie signed an Acknowledgment Form, dated August 18, 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 against Respondent”;
- During a subsequent two-part inspection of Respondent’s business establishment, at approximately 4:26 p.m. on October 2, 2014, at Respondent’s business establishment, 8101 Fenton Street, Silver Spring, Maryland 20910, FDA-commissioned inspectors documented Respondent’s staff selling a package of Newport Box cigarettes 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.

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

Respondent 7-Eleven Store 22921A has not disputed these allegations. Therefore, I find that these facts establish Respondent Kuma H. Mamie d/b/a 7-Eleven Store 22921A’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.

## **A. II. Civil Money Penalty**

Pursuant to 21 U.S.C. § 333(f)(9), Respondent 7-Eleven Store 22921A 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 six violations of the Act and its implementing regulations within a forty-eight month period. Complaint ¶¶ 1, 15. In its Informal Brief, CTP continues to assert that an \$11,000 civil money penalty is appropriate. Informal Brief of Complainant at 9.

Respondent 7-Eleven Store 22921A contends that "the civil money penalty suggested by CTP, if imposed, will have a significant negative impact on Respondent's ability to continue to do business." Informal Brief of Respondent at 4, 5. Respondent goes on to state that "Respondent's net profit for 2012, 2013, and 2014 was only [REDACTED], [REDACTED], and [REDACTED] respectively... Respondent's projected net earnings for 2015 will be less than 2014. An \$11,000 civil penalty would be a death blow to the business." Informal Brief of Respondent at 5. Additionally, Respondent states that "on the prior infractions[,] which Respondent admitted, Respondent was given the name of the employee who committed the alleged infraction." *Id.* Essentially, Respondent is asserting that he has not been allowed take disciplinary action against the employee or implement additional steps to ensure compliance because he has not been given the employee's name.

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**

Respondent 7-Eleven Store 22921A has consistently failed to comply with the Act and its implementing regulations. Respondent previously admitted to and was

found liable for three violations for selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and 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). 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 an \$11,000 civil money penalty against Respondent 7-Eleven Store 22921A. In its production of documents, Respondent 7-Eleven Store 22921A provided CTP with tax returns for 2012, 2013 and 2014. CTP states that Respondent reported gross profits of [REDACTED], [REDACTED], and [REDACTED] respectively. Additionally, CTP states that Respondent had adjusted gross incomes of [REDACTED], [REDACTED], and [REDACTED] respectively from 2012 – 2014.

Respondent states that net profits for 2012, 2013, and 2014 were only [REDACTED], [REDACTED], and [REDACTED] respectively. In addition, Respondent asserts that projected net earnings for 2015 will be less than 2014. Finally, Respondent asserts that an \$11,000 civil penalty would be a death blow to the business.

Considering Respondent's explanation of these figures, imposition of an \$11,000 penalty would take away nearly half of Respondent's net profits, a severe punishment.

**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 7-Eleven Store 22921A's ability to do business. CTP asserts that "[a]n \$11,000 civil monetary penalty will not affect Respondent's ability to do business. Respondent may continue to sell tobacco products and other products at the establishment." Informal Brief of Complainant at 12. While the record does not include specific evidence to show the effects of an \$11,000 civil money penalty, it appears that a civil money penalty of this amount will 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 7-Eleven Store 22921A for violations of the Act and its implementing regulations. In the first civil money penalty action, CRD Docket Number C-13-973, FDA Docket Number FDA-2013-H-0809, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age,

21 C.F.R. § 1140.14(a), on August 2, 2012, and December 13, 2012. On December 13, 2012, Respondent also violated the requirement that retailers 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). An Initial Decision and Default Judgment was entered against Respondent on September 26, 2013. The Initial Decision and Default Judgment became final and binding on the parties on October 26, 2013.

In the second civil money penalty action, CRD Docket Number C-14-1400, FDA Docket Number FDA-2014-H-0904, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on November 19, 2013. Respondent settled the civil money penalty action with CTP for an undisclosed penalty amount.

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), and two failures<sup>2</sup> to verify the identification of persons who were not over the age of 26, in violation of 21 C.F.R. § 1140.14(b)(1). Informal Brief of Complainant at 12. 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 to comply with the federal tobacco regulations calls for a more severe penalty.

**v. Degree of Culpability**

Respondent 7-Eleven Store 22921A admitted to all violations in its informal brief. Based on Respondent 7-Eleven Store 22921A's own admissions, I hold it fully culpable for all six violations of the Act and its implementing regulations.

**vi. Additional Mitigating Factors**

Respondent 7-Eleven Store 22921A stated that "I was not able to identify what employee committed the infraction. This made it difficult for me to identify how the corrective actions I took after the previous violations failed or to take appropriate corrective action with the employee who committed the infraction." Declaration of Kuma H. Mamie ¶ 6.

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<sup>2</sup> CTP asserts in its Informal Brief that Respondent violated 21 C.F.R. § 1140.14(b)(1) three times. The record does not support a finding that Respondent violated 21 C.F.R. § 1140.14(b)(1) three times. The record supports two violations of 21 C.F.R. § 1140.14(b)(1) on December 13, 2012 and October 2, 2014.

**vii. Penalty**

I acknowledge the financial strain a large penalty amount will have on Respondent's small business. Based on the financial strain an \$11,000 penalty would have on Respondent and the foregoing discussion, I find a reduced penalty amount of \$5,500 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 \$5,500 against Respondent, Kuma H. Mamie d/b/a 7-Eleven Store 22921A, for six 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/

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Catherine Ravinski  
Administrative Law Judge