

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Marina Sweet Shop, Inc.,

Respondent.

Docket No. C-13-842  
FDA Docket No. FDA-2013-H-0650

Decision No. CR2857

Date: July 17, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, Marina Sweet Shop, Inc., that alleges facts and legal authority sufficient to justify imposing a \$2,000 civil money penalty. Respondent did not timely answer the Complaint, nor did Respondent request an extension of time within which to file an answer. Therefore, I enter a default judgment against Respondent and assess a civil money penalty of \$2,000.

CTP began this case by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management and serving the Complaint on Respondent. The Complaint alleges that, on two separate occasions, Respondent unlawfully sold a tobacco product to a minor and failed to verify that the purchaser of the tobacco product was of sufficient age, and on one of those occasions also unlawfully sold an individual cigarette, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301-399d, and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil monetary penalty of \$2,000 for these violations.

On June 5, 2013, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, an Administrative Law Judge could issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation or timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true[] and, if such facts establish liability under [the Act],” issue an initial decision by default and impose a civil monetary penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Marina Sweet Shop, an establishment that sells tobacco products and is located at 202 Washington Place, Passaic, New Jersey 07055. Complaint ¶ 3.
- On December 1, 2012, an FDA-commissioned inspector observed two violations at Marina Sweet Shop. First, “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 3:05 PM ET[.]” The inspector also noted that “the minor’s identification was not verified before the [December 1, 2012,] sale . . . .” Complaint ¶ 10.
- “[O]n December 5, 2012, CTP issued a Notice of Compliance Check Inspection” informing Respondent that, on December 1, 2012, an inspector had visited and observed a minor enter the establishment and purchase a tobacco product at approximately 3:03 PM. The Notice warned “that other potential violations of federal tobacco law may have been observed,” and, if violations had occurred, FDA could notify Respondent further. Complaint ¶ 10.
- “[O]n January 3, 2013, CTP issued a Warning Letter to Marina’s<sup>[1]</sup>Sweet Shop.” The letter informed Respondent of the violations the FDA-commissioned inspector had observed on December 1, 2012, and explained that FDA could initiate a civil money penalty or other regulatory action if Respondent failed to

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<sup>1</sup> The caption of the Complaint names Respondent as Marina Sweet Shop. Evidently, the references to “Marina’s Sweet Shop” are typographical errors in the body of the Complaint, and I can infer that they refer to Respondent Marina Sweet Shop.

correct the violations. Moreover, CTP explained that the Warning Letter was not intended to provide an exhaustive list of violations and that Marina's Sweet Shop was responsible for complying with the law. Complaint ¶ 10.

- Respondent responded in writing to the Warning Letter on January 28, 2013. Respondent explained “that the establishment had trained its employees on the rules and regulations regarding the sale of tobacco products, including what types of identification are acceptable for age-verification purposes.” Respondent also assured “that the establishment’s employees would be checking identification of tobacco purchasers under the age of 27.” Complaint ¶ 11.
- On March 27, 2013, CTP acknowledged that it had received Respondent’s response. CTP also reminded Respondent that it had a continuing duty to comply with the law. Complaint ¶ 11.
- During a following inspection, FDA-commissioned inspectors documented three additional violations. First, in violation of 21 C.F.R. § 1140.14(a), “a person younger than 18 years of age was able to purchase an individual cigarette on April 13, 2013, at approximately 12:57 PM[.]” Second, in violation of 21 C.F.R. § 1140.14(b)(1), “the minor’s identification was not verified before the [April 13, 2013,] sale . . . .” Finally, the inspectors cited Respondent for “[s]elling individual cigarettes,” during the two-part inspection conducted on April 13 and April 23, 2013, in violation of 21 C.F.R. § 1140.14(d). Complaint ¶ 1.

Taking these facts as true, I must find, pursuant to 21 C.F.R. § 17.11(a), that Respondent is liable 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, codified at 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Those regulations prohibit the sale of “cigarettes or smokeless tobacco to any person younger than 18 years of age[.]” 21 C.F.R. § 1140.14(a). Those regulations also require a retailer to “verify by means of photographic identification containing the bearer’s date of birth that no person purchasing the [tobacco] product is younger than 18 years of age[.]” 21 C.F.R. § 1140.14(b)(1). Finally, the regulations prohibit retailers from opening a cigarette or smokeless tobacco package “to sell or distribute individual cigarettes . . . .” 21 C.F.R. § 1140.14(d).

Here, Respondent violated 21 C.F.R. § 1140.14(a) and (b)(1) on two separate occasions. First, on December 1, 2012, Respondent unlawfully sold a tobacco product to a minor without verifying that the purchaser was not younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a) and (b)(1). Then, on April 13, 2013, Respondent again sold a tobacco product to a minor without verifying that the minor was of sufficient age. And, during that two-part inspection, Respondent sold an individual cigarette. Therefore,

Respondent's actions and omissions on two separation occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited.

The regulations require me to impose a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a). Respondent has committed its fifth violation within a 36-month period, the maximum penalty for which is \$5,000. 21 C.F.R. § 17.2. CTP, however, has requested a civil money penalty in the amount of \$2,000, which is the maximum penalty for the fourth violation committed within a 24-month period. Therefore, I impose a civil money penalty in the amount of \$2,000.

  /s/    
Steven T. Kessel  
Administrative Law Judge