

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Mashiana Paradise Plaza, Inc.,

Respondent.

Docket No. C-13-899  
FDA Docket No. FDA-2013-H-0726

Decision No. CR2884

Date: August 9, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, Mashiana Paradise Plaza, Inc., alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,000. 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 order that Respondent pay a civil money penalty in the amount of \$2,000.

CTP began this case by serving the Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent's staff unlawfully sold regulated tobacco products to a minor on two separate occasions, failed to verify that the tobacco purchasers were of sufficient age prior to those transactions and impermissibly used a self-service display in a non-exempt facility, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing

regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$2,000.

On June 19, 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, pursuant to 21 C.F.R. § 17.11, issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. Respondent did not take any of the required actions within the time provided by regulation.

I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty, and the respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the Complaint and Respondent's failure to answer them.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Mashiana Paradise Plaza, an establishment that sells tobacco products and is located at 486 South 50 East Bypass 31, Rochester, Indiana 46975.
- On June 16, 2012, an FDA-commissioned inspector observed two violations of regulations found at 21 C.F.R. Part 1140 while inspecting Respondent's establishment. First, Respondent violated 21 C.F.R. § 1140.14(a) when Respondent's staff sold tobacco products to a minor. Specifically, a person younger than 18 years of age was able to purchase a package of "Camel Blue" cigarettes at approximately 2:17 PM. Second, during this same transaction, Respondent's staff violated 21 C.F.R. § 1140.14(b)(1) when Respondent's staff failed to verify, by means of photographic identification containing the bearer's date of birth, that the tobacco purchaser was 18 years of age or older.
- On August 23, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from June 16, 2012. In addition to describing the violations, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against

Respondent if Respondent failed to correct the violations. The letter also stated that it was Respondent's responsibility to comply with the law.

- On September 24, 2012, Preeti Mashiana responded in writing to the Warning Letter on behalf of Respondent. In her letter, Ms. Mashiana stated that "the sale was 'an oversight by the employee selling the cigarettes.'" She also stated that "the establishment will retrain all employees regarding the importance of checking photo IDs for any individual under the age of 30."
- On December 9, 2012, FDA-commissioned inspectors documented additional violations during another inspection of Respondent's establishment. Specifically, at 3:02 PM ET, Respondent's staff sold a package of "Grizzly Long Cut Wintergreen" smokeless tobacco to a person younger than 18 years of age. In addition, Respondent's staff failed to verify the minor's photographic identification prior to this transaction as required by 21 C.F.R. § 1140.14(b)(1). The inspectors also noted a violation of 21 C.F.R. § 1140(c) because Respondent's establishment contained a tobacco self-service display yet the facility did not qualify as one where minors are not permitted to enter at any time,

These facts establish 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. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age. Finally, under 21 C.F.R. § 1140.16(c), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. A self-service display is a method of sale that is not permitted under the regulations. However, self-service displays are permitted in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. *See* 21 C.F.R. § 1140.16 (c)(ii).

Here, Respondent's staff sold cigarettes or smokeless tobacco to a minor on two separate occasions, June 16, 2012, and December 9, 2012. Prior to these transactions, Respondent's staff did not verify, by checking the tobacco purchaser's photographic identification, that the tobacco purchasers were 18 years of age or older as required by the regulations. In addition, Respondent's establishment contained a tobacco self-service display but was not exempt from the requirement that its staff sell tobacco products only through a direct, face-to-

face exchange because minors were permitted to enter the establishment. Respondent's actions and omissions on two separate occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited. Accordingly, I find that a civil money penalty of \$2,000 is permissible under 21 C.F.R. § 17.2 and order one imposed.

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/s/  
Steven T. Kessel  
Administrative Law Judge