

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Double AA Shah Inc.
d/b/a Shah Food Mart #2,

Respondent.

Docket No. C-14-38
FDA Docket No. FDA-2013-H-1248

Decision No. CR3048

Date: December 23, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Double AA Shah Inc. d/b/a Shah Food Mart #2, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. 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 \$500.

CTP began this case by serving a 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 cigarettes to minors and failed to verify that the cigarette purchasers were of sufficient age, 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 \$500.

On October 24, 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 has not filed an answer within the time provided by regulation, nor has it requested an extension. Therefore, pursuant to 21 C.F.R. § 17.11(a), I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

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 Shah Food Mart #2, an establishment that sells tobacco products and is located at 601 Texas Avenue, Texas City, Texas 77590. Complaint ¶ 3.
- On January 21, 2013, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Camel Crush Regular Fresh cigarettes . . . at approximately 12:36 PM CT[.]” The inspector also noted that “the minor’s identification was not verified before the sale . . . on January 21, 2013” Complaint ¶ 10.
- On February 7, 2013, CTP issued a Warning Letter to Shah Food Mart #2 explaining that the inspector’s January 21, 2013 observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1). 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 it failed to correct the violations. The letter also stated that it was Respondent’s responsibility to comply with the law. Complaint ¶ 10.
- On February 14, 2013, Noman Shah, Respondent’s owner, responded in writing to the Warning Letter on Respondent’s behalf. “Mr. Shah stated that he will make sure that his employees do not fail to check an underage customer’s ID again.” Complaint ¶ 11.

- On May 24, 2013, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 during another inspection of Respondent's establishment. The inspectors noted that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . at approximately 7:17 PM[.]" The inspectors also noted that "the minor's identification was not verified before the sale . . . on May 24, 2013" Complaint ¶ 1.

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), retailers are prohibited from selling cigarettes 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 cigarette purchasers are younger than 18 years of age.

Here, Respondent violated 21 C.F.R. § 1140.14(a) on January 21, 2013, and May 24, 2013, when its staff sold cigarettes to minors. Respondent also violated 21 C.F.R. § 1140.14(b)(1) on those same dates when its staff did not verify, by checking the cigarette purchasers' photographic identification, that the cigarette purchasers were 18 years of age or older. Therefore, 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 \$500 is permissible under 21 C.F.R. § 17.2.

/s/
Steven T. Kessel
Administrative Law Judge