

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Raed Iwais / Rafat Iwies  
d/b/a Sunoco,

Respondent.

Docket No. C-14-1217  
FDA Docket No. FDA-2014-H-0719

Decision No. CR3318

Date: August 6, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Raed Iwais / Rafat Iwies d/b/a Sunoco, alleging facts and legal authority sufficient to justify imposing 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 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. pt. 1140. CTP seeks a civil money penalty of \$500.

On June 11, 2014, 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 Sunoco, an establishment that sells tobacco products and is located at 21435 West 8 Mile Road, Detroit, Michigan 48219. Complaint ¶ 3.
- During an inspection of the establishment conducted on March 9, 2013, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 12:04 PM [.]” The inspector also observed that “the minor’s identification was not verified before the sale . . . .” Complaint ¶ 10.
- On June 27, 2013, CTP issued a Warning Letter to Sunoco explaining that the inspector’s March 9, 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 August 27, 2013, Raed Iwais, Respondent’s co-owner and manager, responded by telephone to the Warning Letter. “Mr. Iwais indicated that he would amend the establishment’s policy to require employees to verify the

identification of all tobacco purchasers under the age of 27, and that he would train employees on this policy.” Complaint ¶ 11.

- On November 2, 2013, during a subsequent inspection of Respondent’s establishment, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes . . . at approximately 2:30 PM[.]” The inspectors also noted that “the minor’s identification was not verified before the sale . . . .” 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), no retailer may sell cigarettes to a 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 March 9, 2013, and November 2, 2013, when its staff sold cigarettes to minors. Respondent also violated 21 C.F.R. § 1140.14(b)(1) on those dates, when its staff did not verify, by checking the minors’ photographic identification, that these tobacco 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 that warrant a civil money penalty. Accordingly, I find that a civil money penalty of \$500 is permissible under 21 C.F.R. § 17.2.

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/s/  
Steven T. Kessel  
Administrative Law Judge