

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Guevara LLC  
d/b/a Franklin Package Store,

Respondent.

Docket No. C-13-1110  
FDA Docket No. FDA-2013-H-0914

Decision No. CR2934

Date: September 30, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Guevara LLC d/b/a Franklin Package Store, 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 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 minors on two separate occasions and failed to verify that the tobacco purchasers were of sufficient age prior to these transactions, 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 August 15, 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. I conclude that it is 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 Franklin Package Store, an establishment that sells tobacco products and is located at 402 Franklin Avenue, Hartford, Connecticut 06114. Complaint ¶ 3.
- On August 3, 2012, an FDA-commissioned inspector observed violations of 21 C.F.R. Part 1140 while inspecting Respondent's establishment. Respondent violated 21 C.F.R. § 1140.14(a) when Respondent's staff "[sold] tobacco products to a minor[;] . . . [s]pecifically, a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 2:17 PM ET . . ." Respondent's staff also violated 21 C.F.R. § 1140.14(b)(1) when the staff "[f]ail[ed] to verify the age of a person purchasing tobacco products[,] by means of photographic identification containing the bearer's date of birth[,] . . . before the sale . . . on August 3, 2012 . . ." Complaint ¶ 10.
- On October 18, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from August 3, 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. Complaint ¶ 10.

- The FDA did not receive a response to the Warning Letter, but United Parcel Service records show that “BATISTA J” received the letter on October 19, 2012. Complaint ¶ 11.
- On January 4, 2013, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 at Respondent’s establishment. Specifically, at approximately 10:32 AM ET, Respondent’s staff sold a package of Newport Box 100s cigarettes to a person younger than 18 years of age. In addition, Respondent’s staff did not verify the minor’s age by checking the minor’s photo identification prior to this sale, as required by 21 C.F.R. § 1140.14(b)(1). 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 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 purchaser of cigarettes or smokeless tobacco is younger than 18 years of age.

Here, Respondent’s staff sold cigarettes to minors on two separate occasions: August 3, 2012, and January 4, 2013. Prior to these transactions, Respondent’s staff did not verify, by checking the tobacco purchaser’s photographic identification, that the tobacco purchaser was 18 years of age or older as the regulations require. 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 and order one imposed.

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/s/  
Steven T. Kessel  
Administrative Law Judge