

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Fidel Ruiz Magana
d/b/a Carniceria La Constancia,

Respondent.

Docket No. C-14-326
FDA Docket No. FDA-2013-H-1547

Decision No. CR3116

Date: February 11, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Fidel Ruiz Magana d/b/a Carniceria La Constancia, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 \$250.

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, 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 \$250.

On December 18, 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 Carniceria La Constancia, an establishment that sells tobacco products and is located at 1109 East Main Street #103, Mesa Arizona 85203. Complaint ¶ 3.
- On February 14, 2013, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Marlboro 100’s cigarettes . . . at approximately 11:34 AM.” Complaint ¶ 10.
- On March 7, 2013, CTP issued a Warning Letter to Carniceria La Constancia explaining that the inspector’s February 14, 2013 observation constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a). In addition to describing the violation, 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 violation. The letter also stated that it was Respondent’s responsibility to comply with the law. Complaint ¶ 10.
- On June 3, 2013, Fidel Ruiz, Respondent’s owner, responded in writing to the Warning Letter on Respondent’s behalf. “Mr. Ruiz stated that all cashiers have instructions for verifying the identification of a customer who is purchasing cigarettes. . . . [and] that all cashiers were notified of the incident and were warned that disciplinary action would be taken against a cashier for any future violations.” Complaint ¶ 11.

- On June 20, 2013, FDA-commissioned inspectors documented a violation of 21 C.F.R. § 1140.14(a) 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 Camel Crush cigarettes . . . at approximately 1:27 PM.” 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 any person younger than 18 years of age.

Here, Respondent violated 21 C.F.R. § 1140.14(a) on February 14, 2013, and June 20, 2013, when its staff sold cigarettes to minors. Respondent’s actions 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 \$250 is permissible under 21 C.F.R. § 17.2.

/s/
Steven T. Kessel
Administrative Law Judge