

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Maribel Padilla

d/b/a Cecilia's Convenience Store / 99 Cent Store,

Respondent.

Docket No. C-13-451

FDA Docket No. FDA-2013-H-0207

Decision No. CR2858

Date: July 17, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, Maribel Padilla d/b/a Cecilia's Convenience Store / 99 Cent Store, alleging facts and legal authority sufficient to justify imposing 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 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 or minors on two separate occasions, 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 June 3, 2013, CTP served the Complaint on Respondent by personal delivery, 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 and default judgment 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 Cecilia's Convenience Store / 99 Cent Store, an establishment that sells tobacco products and is located at 9354 West Van Buren Street, Tolleson, Arizona 85353.
- On January 4, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.14(a) when Respondent's staff sold cigarettes or smokeless tobacco to a person younger than 18 years of age.
- On February 23, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from January 4, 2012. 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 Respondent failed to correct the violation. The letter also stated that it was Respondent's responsibility to comply with the law.
- On February 29, 2012, Maribel Padilla, the owner of 99 Cent Store, responded by telephone to CTP's Warning Letter on behalf of Respondent. Ms. Padilla stated that she would discuss the tobacco sales laws with her employee and change the store's tobacco sales policy to include "requesting

ID of persons under age 27 and refusing to sell tobacco products to minors.”

- On November 16, 2012, FDA-commissioned inspectors documented an additional violation during another inspection of Respondent’s establishment. At approximately 10:01 AM MT, Respondent’s staff sold a package of “Marlboro” cigarettes to a person younger than 18 years of age.

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.

Here, Respondent’s staff sold cigarettes or smokeless tobacco to a minor or minors on two separate occasions, January 4, 2012, and November 16, 2012. Respondent’s actions on two 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 \$250 is permissible under 21 C.F.R. § 17.2 and order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge