

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Angelica Sanchez
d/b/a Deli Latino,

Respondent.

Docket No. C-14-1887
FDA Docket No. FDA-2014-H-1374

Decision No. CR3449

Date: November 10, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Angelica Sanchez d/b/a Deli Latino, 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 a minor, 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 September 17, 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 issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

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 Deli Latino, an establishment that sells tobacco products and is located at 3133 Eastern Avenue, Baltimore, MD 21224. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-14-415, FDA Docket Number FDA-2013-H-1627, against Respondent for two violations of 21 C.F.R. pt. 1140 within a 12-month period. Specifically, those violations included an unspecified violation on February 6, 2013, and a violation on June 3, 2013, when Respondent sold tobacco products to a minor. Complaint ¶ 10.
- The previous civil money penalty action concluded when Angelica Sanchez, Respondent's authorized representative, settled the action with CTP on Respondent's behalf. On January 13, 2014, Ms. Sanchez signed an Acknowledgment Form in which she "admitt[ed] that the violations . . . occurred, waiv[ed] Respondent's ability to contest the violations in the future, and stat[ed] that she understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions against Respondent." The Administrative Law Judge closed the case on February 24, 2013. Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment conducted on March 13, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Marlboro 100's cigarettes . . . at approximately 1:11 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). The regulations prohibit the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

Here, Respondent had three violations of regulations found at 21 C.F.R. pt. 1140 within a 24-month period. Respondent acknowledged that two violations occurred when its representative settled the previous civil money penalty action. Most recently, on March 13, 2013, Respondent sold cigarettes to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$500, which is a permissible fine for three violations of the regulations found at 21 C.F.R. pt. 1140. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge