

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

C Store, L.L.C.
d/b/a Selah Mini Mart and Smoke Shop,

Respondent.

Docket No. C-14-1687
FDA Docket No. FDA-2014-H-1174

Decision No. CR3416

Date: October 15, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, C Store, L.L.C. d/b/a Selah Mini Mart and Smoke Shop 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 tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that a tobacco purchaser was 18 years of age or older, 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 August 18, 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 Selah Mini Mart, an establishment that sells tobacco products and is located at 103 South First Street, Selah, Washington 98942. Complaint ¶ 3.
- During an inspection of Respondent's establishment on May 7, 2013, at approximately 6:22 PM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]” The inspector also observed that “the minor’s identification was not verified before the sale” Complaint ¶ 10.
- On May 23, 2013, CTP issued a Warning Letter to Respondent regarding the inspector's observations from May 7, 2013. The letter explained that the observations constituted a violation of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- By letter, on August 21, 2013, Respondent's Site Manager, responded to the Warning Letter on Respondent's behalf. “The site manager stated that the store's ‘system has been updated’ and that employees are trained to check for identification for tobacco sales.” Complaint ¶ 11.

- During a subsequent inspection of Respondent's establishment conducted on February 21, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 10:48 AM[.]" The inspectors also documented 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). 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). The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on May 7, 2013 and February 21, 2014. On those same dates, Respondent violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). 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 under the regulations. 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