

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Phoenix Smoke Shops LLC
d/b/a 55th Avenue Smoke Shop,

Respondent.

Docket No. C-13-578
FDA Docket No. FDA-2013-H-0356

Decision No. CR2782

Date: May 13, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Phoenix Smoke Shops LLC d/b/a 55th Avenue Smoke Shop, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$5,000. 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 \$5,000.

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 sold cigarettes or smokeless tobacco in a manner other than a direct, face-to-face exchange with its customer; failed to ensure specific tobacco-related items complied with applicable federal regulations; sold tobacco products to a minor or minors; and failed to

verify, by means of photographic identification containing the bearer's date of birth, the age of a person purchasing tobacco products, 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 \$5,000.

On March 29, 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, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision 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 a 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 55th Avenue Smoke Shop, a business that sells tobacco products and is located at 5540 West Glendale Avenue, Glendale, Arizona 85301.
- On October 18, 2011, an FDA-commissioned inspector observed violations while inspecting Respondent's establishment. Specifically, Respondent violated 21 C.F.R. § 1140.16(c)(1) and (c)(2)(ii) when Respondent's staff sold cigarettes or smokeless tobacco in a manner other than a direct, face-to-face exchange with its customer in a facility that fails to ensure that no person younger than 18 years of age is present, or permitted to enter, at any time. Respondent also violated 21 C.F.R. § 1140.14(e) when it failed to either ensure specific tobacco-related items complied with applicable federal regulations or remove those items from the establishment.
- On December 22, 2011, CTP issued a Warning Letter to Respondent detailing the inspector's observations from October 18, 2011. 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.

- On December 29, 2011, Mr. Ramey Sweis responded, by telephone, to the Warning Letter on behalf of Respondent. Mr. Sweis stated that all cigarette tobacco products would be removed from the self-service display and placed behind the counter.
- On January 26 and 30, 2012, FDA-commissioned inspectors documented additional violations during another inspection of Respondent's establishment. Specifically, Respondent violated 21 C.F.R. § 1140.14(a) when Respondent's staff sold tobacco products to a minor, and violated 21 C.F.R. § 1140.14 (b)(1) when Respondent's staff did not verify the minor's identification, by means of photographic identification containing the bearer's date of birth, before this sale.
- On June 11, 2012, CTP initiated a civil money penalty action against Respondent for the violations observed on October 18, 2011, and January 26 and 30, 2012. In response to the action, Respondent paid the penalty and the Administrative Law Judge closed the case on August 14, 2012.
- On November 16, 2012, FDA-commissioned inspectors documented additional violations during another inspection of Respondent's establishment. Specifically, at approximately 12:21 p.m., a person younger than 18 years of age was able to purchase a package of "Top Regular Superroll" cigarette tobacco. Additionally, Respondent's staff did not verify the minor's identification, by means of photographic identification containing the bearer's date of birth, before this sale.
- On November 21, 2012, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment. This notice informed Respondent that an inspection was conducted on November 16, 2012, and detailed the violations that the inspectors observed during the inspection.

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. § 1140.16(c)(1), a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays. However, vending machines and self-service displays are

permitted if located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. 21 C.F.R. § 1140.16(c)(2)(ii). Under 21 C.F.R. § 1140.14(e), retailers must ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of 21 C.F.R. Part 1140 are removed or are brought into compliance with that part. 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. Finally, 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 person purchasing cigarettes or smokeless tobacco is younger than 18 years of age.

Here, Respondent's staff sold cigarettes or smokeless tobacco in a manner other than a direct, face-to-face exchange with its customer on October 18, 2011. On that date, Respondent's establishment was not exempt from the requirement that tobacco products be sold only via a direct, face-to-face exchange because minors were permitted to enter the establishment. Additionally, on October 18, 2011, Respondent failed to ensure specific tobacco-related items complied with applicable federal regulations. During two later inspections, one on January 26 and 30, 2012, and another on November 16, 2012, Respondent's staff sold cigarettes or smokeless tobacco to a minor or minors. Lastly, Respondent's staff did not check the photographic identification of the tobacco purchasers prior to these transactions as required by the regulations. Respondent's actions and omissions on multiple 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 \$5,000 is permissible under 21 C.F.R. § 17.2 for at least five violations of 21 C.F.R. Part 1140 within a thirty-six month period.

/s/

Steven T. Kessel
Administrative Law Judge