

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Mae B., Inc.
d/b/a Turnpike Spirit Shop,

Respondent.

Docket No. C-13-315
FDA Docket No. FDA-2013-H-0086

Decision No. CR2720

Date: March 11, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Mae B., Inc. d/b/a Turnpike Spirit Shop, alleging facts and legal authority sufficient to justify the imposition of 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 impermissibly sold tobacco products to a minor and failed to appropriately verify 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 \$500.

On January 28, 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 one 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 Turnpike Spirit Shop, a business that sells tobacco products and is located at 1838 Black Rock Turnpike, Fairfield, Connecticut 06825.
- On December 22, 2011, an FDA-commissioned inspector observed a violation at Respondent's establishment, namely, Respondent sold cigarettes or smokeless tobacco to a person younger than 18 years of age.
- On February 9, 2012, CTP issued a Warning Letter to Turnpike Spirit Shop & Wine Emporium regarding the inspector's observations from December 22, 2011. The letter stated that the observations constituted a violation of regulations at 21 C.F.R. § 1140.14(a) and that these regulations prohibit the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age. The letter also advised Respondent that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by FDA.
- On July 25, 2012, FDA commissioned inspectors documented additional violations during a subsequent inspection of the establishment. At approximately 3:05 P.M. ET, a minor under the age of 18 was able to buy a

package of “Marlboro Red Label” cigarettes. Additionally, the minor’s identification was not verified, by means of photographic identification containing the bearer’s date of birth, before this sale.

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. 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 the tobacco product is younger than 18 years of age.

Here, Respondent sold tobacco products to a minor in violation of the foregoing regulations on two separate occasions. Most recently, on July 25, 2012, at Turnpike Spirit Shop, Respondent sold tobacco products to a minor and failed to appropriately verify the minor’s age prior to the sale. The Complaint alleges a previous violation on December 22, 2011, also for the sale of tobacco products to a minor. CTP alleges that this violation occurred at Turnpike Spirit Shop & Wine Emporium. Although the Complaint does not state that Turnpike Spirit Shop & Wine Emporium is also known as or is a prior name of Turnpike Spirit Shop, I infer that the two names refer to the same retail outlet. Therefore, Respondent’s actions and omissions on two separate 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 \$500 is permissible under 21 C.F.R. § 17.2.

/s/

Steven T. Kessel
Administrative Law Judge