

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Vandu, Inc.
d/b/a Romeoville Shell,

Respondent.

Docket No. C-13-224
FDA Docket No. FDA-2012-H-1229

Decision No. CR2700

Date: January 31, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent that alleges facts and legal authority sufficient to justify the imposition of a \$250 civil money penalty. 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, Vandu, Inc. d/b/a Romeoville Shell, and assess a civil money penalty of \$250.

CTP began this case by serving the Complaint on Respondent and filing a copy of the same with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent impermissibly sold tobacco products to a minor 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 for these two violations.

On December 24, 2012, 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 ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has neither filed an Answer within the time provided by regulation nor timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true, and, if such facts establish liability under [the Act],” issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Romeoville Shell, an establishment that sells tobacco products and is located at 1 Alexander Circle, Romeoville, Illinois 60446. Complaint ¶ 3.
- On December 21, 2011, an FDA-commissioned inspector performed an inspection of Shell Food Mart and observed the “sale of cigarettes or smokeless tobacco to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a).” Complaint ¶ 10.
- CTP issued a warning letter to Shell Food Mart on February 9, 2012, informing Respondent of the violation that the FDA-commissioned inspector had observed on December 21, 2011, at that establishment. The letter advised that it was not intended to provide an exhaustive list of violations and that the failure to correct violations could result in the imposition of a civil money penalty or other regulatory action. Moreover, the letter informed Respondent that Shell Food Mart maintained the responsibility to ensure that it complied with the law. Complaint ¶ 10.
- United Parcel Service records indicate that “Patel” received the February 9, 2012 warning letter on February 20, 2012, but Respondent did not contact CTP in response thereto. Complaint ¶ 11.
- Pursuant to a two-part inspection of Romeoville Shell, FDA-commissioned inspectors noted that “a person younger than 18 years of age was able to

purchase a package of Newport Box cigarettes on August 9, 2012, at approximately 11:16 AM CT[,]” in violation of 21 C.F.R. § 1140.14(a). Complaint ¶ 1.

- Thereafter, on August 14, 2012, CTP informed Respondent of the August 9, 2012, inspection and documented violation through a Notice of Compliance Check Inspection. The Notice warned “that other potential violations of federal tobacco law may have been observed,” and that FDA may notify Respondent if it determined there had been violations of federal law. Complaint ¶ 2.

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 distributed or offered for sale in any state 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 Secretary issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. 387(a); 21 U.S.C. § 387f(d)(1); *75 Fed. Reg.* 13,229 (Mar. 10, 2010). 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 sold tobacco products to a minor in violation of the foregoing regulations on two separate occasions. Most recently, Respondent sold tobacco products to a minor at Romeoville Shell on August 9, 2012. The Complaint alleges a previous violation on December 21, 2011, also for the sale of tobacco products to a minor. CTP alleges that this violation occurred at Shell Food Mart. Although the Complaint does not state that Shell Food Mart is also known as or is a prior name of Romeoville Shell, I infer that the two names refer to the same retail outlet. Therefore, Respondent’s actions on two separate occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited.

The regulations require the imposition of a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a)(1)-(2). CTP has requested and the regulations authorize a penalty of \$250. Complaint ¶ 1; 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge