

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2014-H-0059)

Complainant

v.

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

Respondent.

Docket No. C-14-523

Decision No. CR3157

Date: March 18, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Vandu, Inc. d/b/a Romeoville Shell, at 1 Alexander Circle, Romeoville, Illinois 60446, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Romeoville Shell impermissibly sold tobacco products to a minor, violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. Part 1140. CTP seeks to impose a \$500 civil money penalty against Respondent Romeoville Shell.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 29, 2014, CTP served the complaint on Respondent Romeoville Shell by United Parcel Service. 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 in 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 it to pay the full amount of the proposed penalty.

Respondent has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically, at approximately 6:34 PM on September 25, 2013, at Respondent's business establishment, 1 Alexander Circle, Romeoville, Illinois 60446, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age.

In a decision dated January 31, 2013, which became final on March 2, 2013, the Administrative Law Judge found:

- On December 21, 2011, Respondent's staff sold cigarettes or smokeless tobacco to a person younger than 18 years of age.
- CTP informed Respondent of the alleged December 21, 2011 violation by warning letter dated February 9, 2012.
- On August 9, 2012, Respondent's staff sold a package of Newport Box cigarettes to a person younger than 18 years of age.

*Vandu, Inc. d/b/a Romeoville Shell*, DAB CR 2700, at 2-3 (2013).

These facts establish Respondent Romeoville Shell's liability 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. § 387f(d); *see* 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); *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell tobacco products to any person younger than 18 years of age.

A \$500 civil money penalty is permissible under 21 C.F.R. § 17.2.

**Order**

For these reasons, I enter default judgment in the amount of \$500 against Respondent Vandu, Inc. d/b/a Romeoville Shell. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

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/s/  
Carolyn Cozad Hughes  
Administrative Law Judge