

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Dwinell's B.U., Inc.  
d/b/a Bottoms Up Discount Beverage,

Respondent.

Docket No. C-13-991  
FDA Docket No. FDA-2013-H-0817

Decision No. CR2907

Date: August 29, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Dwinell's B.U., Inc. d/b/a Bottoms Up Discount Beverage, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 assess a civil money penalty of \$250.

CTP began this case by serving the 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 cigarettes to a minor and utilized a self-service display in a violative manner in a non-exempt facility, thereby infringing the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, Cigarettes and

Smokeless Tobacco, 21 C.F.R. Part 1140 (2012). CTP seeks a civil money penalty of \$250.

On July 10, 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 proposed 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, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those 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 the following facts in its Complaint:

- Respondent owns Bottoms Up Discount Beverage, an establishment that sells tobacco products and is located at 637 New Hampshire Route 12 South, Fitzwilliam, New Hampshire 03447. Complaint ¶ 3.
- On December 6, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.16(c) at Respondent’s establishment. The violation resulted from Respondent’s “us[e] [of] a self-service display in a non-exempt facility . . . .” Complaint ¶ 10.
- On January 3, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from December 6, 2012. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.16(c), and that the named violation was not necessarily the only violation at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur. Further, the letter informed Respondent that it is responsible for complying with the law. Complaint ¶ 10.
- Mary Salmi, Respondent’s manager, replied to the Warning Letter on Respondent’s behalf. In her January 7, 2013 letter, Ms. Salmi “stated that

the self-service display was removed, and that cigarettes are not directly accessible to customers.” Complaint ¶ 11.

- On April 10, 2013, at approximately 5:16 PM, FDA-commissioned inspectors documented an additional violation of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspectors documented a violation of 21 C.F.R. § 1140.14(a) when “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . .” Complaint ¶ 1.
- CTP issued a Notice of Compliance Check Inspection to Bottoms Up Discount Beverage on April 12, 2013, due to the minor’s April 10, 2013 cigarette purchase. The Notice stated that the violation described was not necessarily the only violation reported. 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 to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also prohibit the use of self-service displays to sell cigarettes, 21 C.F.R. § 1140.16(c)(1), except in facilities where no individual younger than 18 years of age is present or permitted to enter at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

Taking the above alleged facts as true, Respondent had two violations of regulations contained in 21 C.F.R. Part 1140 within a five-month period. Specifically, Respondent had a violation on December 6, 2012, and a violation on April 10, 2013. Respondent’s actions violated the prohibition against selling cigarettes to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent’s actions also violated the prohibition on the use of self-service displays to sell cigarettes, 21 C.F.R. § 1140.16(c)(1), because it is not a facility that restricts access to persons younger than 18 years at all times, 21 C.F.R. § 1140.16(c)(2)(ii).<sup>1</sup> Therefore, Respondent’s actions constitute violations of law for which a civil money penalty is merited.

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<sup>1</sup> CTP fails to specifically allege that Respondent’s establishment permits individuals younger than 18 years of age to enter the establishment. CTP does, however, allege a violation of 21 C.F.R. § 1140.16(c). In order for Respondent’s use of a self-service display to constitute a violation of 21 C.F.R. § 1140.16(c), Respondent’s establishment must permit persons younger than 18 years of age to enter at some time. Because Respondent failed to answer the Complaint and

