

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

UISCE BEATHA, Inc.
d/b/a Cavanaugh's Restaurant,

Respondent.

Docket No. C-15-566
FDA Docket No. FDA-2014-H-2086

Decision No. CR3587

Date: January 23, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, UISCE BEATHA, Inc. d/b/a Cavanaugh's Restaurant, that alleges facts and legal authority sufficient to justify the imposition of a \$2,000 civil money penalty. Respondent did not 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 \$2,000 civil money penalty.

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 sold cigarettes to minors, failed to verify that cigarette purchasers were 18 years of age or older, and used a vending machine to sell regulated tobacco products in a non-exempt facility, thereby violating 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. pt. 1140 (2013). CTP seeks a civil money penalty of \$2,000.

On December 4, 2014, 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 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 Cavanaugh’s Restaurant, an establishment that sells tobacco products and is located at 119 South 39th Street, Philadelphia, Pennsylvania 19104. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on June 3, 2013, at approximately 5:39 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes from a vending machine . . . [.]” The inspector also observed that “the minor’s identification was not verified before the sale” Complaint ¶ 10.
- On July 3, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from June 3, 2013. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a), (b)(1), and (c), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- Although UPS records indicate that an individual named “Pritchett” received the Warning Letter, CTP did not receive a response to the Warning Letter. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on February 1, 2014, at approximately 1:11 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of

Parliament cigarettes from a vending machine . . . [.]” The inspectors also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 1.

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 of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 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 require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Moreover, under 21 C.F.R. § 1140.14(c), a retailer may sell cigarettes only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device, such as a vending machine. However, vending machines containing cigarettes are permitted 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).

Taking the above alleged facts as true, on June 3, 2013, and February 1, 2014, Respondent violated both 21 C.F.R. § 1140.14(a) and 21 C.F.R. § 1140.14(c) by using a vending machine to sell cigarettes to a minor. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$2,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. I thus find that a civil money penalty of \$2,000 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge