

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Azon Liquors Inc.,

Respondent.

Docket No. C-13-828  
FDA Docket No. FDA-2013-H-0642

Decision No. CR2863

Date: July 19, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, Azon Liquors Inc., that alleges facts and legal authority sufficient to justify imposing a \$500 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 and assess a civil money penalty of \$500.

CTP began this case by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management and serving the Complaint on Respondent. The Complaint alleges that, on two separate occasions, Respondent unlawfully sold a tobacco product to a minor and failed to verify that the purchaser of the tobacco product was of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301-399d, and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil monetary penalty of \$500 for these violations.

On June 3, 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, an Administrative Law Judge could issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation or 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 an initial decision by default and impose a civil monetary penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Azon Liquors, an establishment that sells tobacco products and is located at 384 Walnut Street Extension, Agawam, Massachusetts 01001. Complaint ¶ 3.
- On April 29, 2012, an FDA-commissioned inspector observed two violations at Azon Liquors. First, “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . at approximately 12:56 PM ET[.]” The inspector also noted that “the minor’s identification was not verified before the [April 29, 2012,] sale . . . .” Complaint ¶ 10.
- “[O]n June 21, 2012, CTP issued a Warning Letter to Azon Liquors.” The letter informed Respondent of the violations the FDA-commissioned inspector had observed on April 29, 2012, and explained that the FDA could initiate a civil money penalty or other regulatory action if Respondent failed to correct the violations. Moreover, CTP explained that the Warning Letter was not intended to provide an exhaustive list of violations and that Azon Liquors was responsible for complying with the law. Complaint ¶ 10.
- Respondent’s President, Michael W. Beaudry, responded in writing to the Warning Letter on Respondent’s behalf on June 25, 2012. Mr. Beaudry explained that, during trainings and meetings, “employees are reminded to check identification for customers who look under the age of forty.” Moreover, Mr. Beaudry indicated that “[h]e also instructed his staff to check identification regularly to prevent future violations.” Complaint ¶ 11.

- On October 16, 2012, CTP acknowledged that it had received Respondent's response. CTP also reminded Respondent that it had a continuing duty to comply with the law. Complaint ¶ 11.
- During a following inspection, FDA-commissioned inspectors documented two additional violations. "Specifically, a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on November 10, 2012, at approximately 12:08 PM ET[.]" And, "the minor's identification was not verified before the [November 10, 2012,] sale . . . ." Complaint ¶ 1.

Taking these facts as true, I must find, pursuant to 21 C.F.R. § 17.11(a), 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, codified at 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Those 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). Those regulations also require a retailer to "verify by means of photographic identification containing the bearer's date of birth that no person purchasing the [tobacco] product is younger than 18 years of age[.]" 21 C.F.R. § 1140.14(b)(1).

Here, Respondent violated 21 C.F.R. § 1140.14(a) and (b)(1) on two separate occasions. First, on April 29, 2012, Respondent unlawfully sold a tobacco product to a minor without verifying that the purchaser was not younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a) and (b)(1). Then, on November 10, 2012, Respondent again sold a tobacco product to a minor without verifying that the minor was of sufficient age. 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.

The regulations require me to impose 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). Respondent has committed its fourth violation within a 24-month period, the maximum penalty for which is \$2000. 21 C.F.R. § 17.2. CTP, however, has requested a civil money penalty in the amount of \$500, which is the maximum penalty for the third violation committed within a 24-month period. Therefore, I impose a civil money penalty in the amount of \$500.

/s/  
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Steven T. Kessel  
Administrative Law Judge