

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

The Bottle Shoppe Inc.,

Respondent.

Docket No. C-13-177
FDA Docket No. FDA-2012-1198

Decision No. CR2690

Date: January 17, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint against Respondent, The Bottle Shoppe Inc., alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2000. 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 \$2000.

CTP began this case by serving a 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 tobacco products to a minor, failed to verify the identification of an individual 26 years of age or younger, and used a self-service display in a non-exempt location, 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. Part 1140 (2012). CTP seeks a civil money penalty of \$2000.

On December 11, 2012, CTP served a 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 complaint 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 The Bottle Shoppe Inc., an establishment that sells tobacco products and is located at 231 North Main Street, Florence, AZ 85232. Complaint ¶ 3.
- On January 31, 2012, an FDA-commissioned inspector observed Respondent violating 21 C.F.R. § 1140.16(c), a regulation prohibiting the use of a self-service display in a non-exempt facility. Complaint ¶ 10.
- On March 8, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from January 31, 2012. The letter explained that the observations constituted a violation of regulations found at 21 C.F.R. § 1140.16(c). The letter further explained that these regulations prohibit the use of self-service displays in any non-exempt facility and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that failure to correct the violation could result in the imposition of a civil money penalty or other regulatory action by the FDA and that Respondent is responsible for complying with the law. *Id.*
- Respondent replied to CTP’s Warning Letter on March 28, 2012, via an electronic mail from Laura Behrens, who identified herself as Respondent’s owner. Ms. Behrens “submitted photographs of the establishment and explained that the store would not permit minors to enter beyond the first

cash register, which would prevent access to all self-service displays.”
Complaint ¶ 11.

- In response to Ms. Behrens’ electronic mail, CTP replied to Respondent by letter on June 11, 2012, and reminded Respondent that it continued to be required to comply with all applicable portions of the Act and its implementing regulations. *Id.*
- On August 7, 2012, CTP issued a Notice of Compliance Check Inspection to The Bottle Shoppe Inc. due to a minor’s purchase of a regulated tobacco product on August 3, 2012, at 11:59 AM. The Notice stated that the violation described was not necessarily the only violation reported and that CTP could either issue a Warning Letter in response to the named violation or seek a civil money penalty. Complaint ¶ 2.
- During the August 3, 2012 inspection, FDA commissioned inspectors documented three violations of the regulations: (1) a violation of 21 C.F.R. § 1140.14(a), as a result of the sale of a package of Marlboro Smooth 100's cigarettes to a minor; (2) a violation of 21 C.F.R. § 1140.14(b)(1), as a result of the same sale without having verified the photo identification of the minor-purchaser; and, (3) a violation of 21 C.F.R. § 1140.16(c), as a result of the same sale, which took place through the use of a self-service display. 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 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). They further prohibit retailers’ sales of cigarettes or smokeless tobacco to persons not over the age of 26 without having verified, by photo identification containing the bearer’s date of birth, that the person purchasing cigarettes or smokeless tobacco is older than 18 years of age. 21 C.F.R. § 1140.14(b)(1)-(2). Finally, the regulations prohibit the use of self-service displays in facilities where the retailer fails to ensure 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)(1) and (c)(2)(ii).

Taking the above alleged facts as true, Respondent had four violations of regulations contained in 21 C.F.R. Part 1140 within a ten month period.

Specifically, Respondent had one violation on January 31, 2012, and three violations on August 3, 2012. Respondent's actions on January 31, 2012, and on August 3, 2012, violated the prohibition on the use of self-service displays in facilities where the retailer fails to ensure that no person younger than 18 years of age is present, or permitted to enter, at any time, because Respondent utilized a self-service display in an establishment in which it allowed a minor to enter. 21 C.F.R. § 1140.16(c)(1) and (c)(2)(ii). Further, Respondent's sale of a package of Marlboro Smooth 100's cigarettes to a minor on August 3, 2012, also violated regulations prohibiting the sale of tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and regulations requiring retailers to verify, by photo identification containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent's actions 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). Therefore, I find that a civil money penalty of \$2000 is warranted and so order one imposed.

/s/

Steven T. Kessel
Administrative Law Judge