

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Brandy Inn, Inc.,

Respondent.

Docket No. C-14-95

FDA Docket No. FDA-2013-H-1304

Decision No. CR3071

Date: January 9, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated the above-captioned matter when it filed an Administrative Complaint for Civil Money Penalties (Complaint) with the Departmental Appeals Board, Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. CTP seeks to impose civil money penalties under the Federal Food, Drug, and Cosmetic Act (Act) and the Act's implementing regulations.

The Complaint alleges the following facts. Respondent owns an establishment that sells tobacco products and is located at 103 Water Street, Cahokia, Illinois 62206. Complaint ¶ 2. CTP conducted two inspections of the establishment. Complaint ¶ 9. During a September 4, 2012, inspection, an FDA-commissioned inspector observed Respondent “[u]sing a vending machine in a non-exempt facility [to sell tobacco products] . . . in a customer[-]accessible part of the establishment, . . . [where] . . . minors [were permitted] to enter”

The inspector also observed that Respondent:

[Sold] misbranded tobacco products through a vending machine. Specifically, . . . [the inspector observed] a vending machine with selection buttons . . . [that were labeled with the names of various cigarettes including] ‘Low in Tar and Nicotine Marlboro Lights,’ . . . [however,] [t]he cigarettes stocked [in the vending machine did not] correspond with the . . . actual [tobacco] product . . . advertis[ed] . . . [on the selection] button[s] . . . [.]

Complaint ¶ 10.

On November 29, 2012, CTP issued a warning letter to Respondent specifying the violations that the inspector observed. The letter warned Respondent that if it failed to correct the violations, civil money penalties could be imposed on it and that it was Respondent’s responsibility to ensure compliance with the law. Complaint ¶ 10.

Arlene Musskopf, Respondent’s owner, replied to the warning letter in a December 28, 2012, telephone call. “Ms. Musskopf stated that the vending machine will be removed within one week.” Complaint ¶ 11.

During a subsequent inspection, conducted on May 7, 2013, and May 8, 2013, FDA-commissioned inspectors documented Respondent:

[U]sing a vending machine in a non-exempt facility . . . [to sell] cigarettes in a customer[-]accessible [area] . . . of the establishment, . . . [where] minors [were allowed] to enter with adults before 8:00 PM.

Complaint ¶ 1.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on November 13, 2013, via United Parcel Service. CTP charged Respondent with violating 21 C.F.R. § 1140.14(c) (utilizing a vending machine to sell tobacco products in a non-exempt facility) and Section 301 of the Act, codified at 21 U.S.C. § 387c, Section 903 of the Act, codified at 21 U.S.C. § 387c (selling misbranded tobacco products). Complaint ¶¶ 1, 10. CTP asked the CRD to impose a \$250 civil money penalty based on two alleged violations of the regulations in a 12-month period. Complaint ¶ 12.

The Complaint provided detailed instructions related to filing an answer and requesting an extension of time to file an answer. Complaint ¶¶ 15-19, 21-23. The Complaint stated that failure to file an answer could result in the imposition of a civil money penalty against Respondent. Complaint ¶ 20. Further, after CTP filed the Complaint, CRD sent Respondent an Initial Order informing Respondent of the requirement to file an answer to avoid a default judgment. CRD sent a form answer along with the Initial Order that Respondent could fill out and file with CRD. Respondent neither filed an answer nor requested an extension of time within the 30-day time period prescribed in 21 C.F.R. § 17.9.

If a respondent does not file an answer within 30 days of a properly served complaint or by the date stated in any extension that the presiding officer may grant, the regulations provide that:

the presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:

- (1) The maximum amount of penalties provided for by law for the violations alleged; or
- (2) The amount asked for in the complaint, whichever amount is smaller.

21 C.F.R. § 17.11(a). Further, a failure to file a timely answer means that “the respondent waives any right to a hearing and to contest the amount of the penalties and assessments” imposed in the initial decision. 21 C.F.R. § 17.11(b).

Accepting the facts alleged in the Complaint as true, I find that those facts establish Respondent’s liability under the Act. *See* 21 U.S.C. §§ 333(f)(9), 387c(a)(7)(B), 387f(d); 21 C.F.R. §§ 1140.1(b), 1140.14. I also find that CTP’s request to impose a \$250 civil money penalty is permissible. *See* 21 C.F.R. § 17.2.

Therefore, Respondent is directed to pay a civil money penalty in the amount of \$250. This initial decision becomes final and binding upon both parties 30 days after the date of its issuance. 21 C.F.R. § 17.11(b).

It is so ordered.

/s/
Joseph Grow
Administrative Law Judge