

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

NTSC, LLC d/b/a Rookies Sports Bar & Grill,

Respondent.

Docket No. C-12-536  
FDA Docket No. FDA-2012-H-0344

Decision No. CR2550

Date: June 11, 2012

**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 Civil Remedies Division 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 in Denver, Colorado that sells tobacco products. CTP conducted inspections of the establishment on April 21, 2011, November 7, 2011, and November 19, 2011. During the April 21, 2011 inspection, an FDA-commissioned inspector observed that Respondent:

Fail[ed] to sell cigarettes or smokeless tobacco in a direct, face-to-face exchange without the assistance of any electronic or mechanical device in a facility that does not ensure that no person younger than 18 years of age is present or permitted to enter, at any time, as required by 21 C.F.R. § 1140.14(c) and 1140.16(c); and

[failed] to ensure that all violative [sic] [were] removed or [were] brought into compliance with requirements of 21 C.F.R. Part 1140, as required by 21 C.F.R. § 1140.14(e).

(Compl. ¶ 10.)

CTP issued a warning letter, received by Respondent on July 19, 2011, specifying the violations that the inspector observed. The letter warned Respondent that a failure to correct violations could result in the imposition of civil money penalties and that it was Respondent's responsibility to ensure compliance with the law. (Compl. ¶ 10.) The CTP did not receive a response to the warning letter. (Compl. ¶ 11.)

During a two-part inspection on November 7, 2011, and November 19, 2011, FDA-commissioned inspectors observed that:

[A] minor was able to enter [Respondent's] facility and attempt to purchase tobacco products from a vending machine. The bartender in the establishment provided the minor change, which the minor then put into the machine. The vending machine malfunctioned and the bartender refunded the minor's money. The bartender commented that the vending machine was "working just fine yesterday."

(Compl. ¶ 9.)

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the complaint on April 11, 2012, via United Parcel Service. CTP charged Respondent with violating 21 C.F.R. § 1140.14(c) (use of a vending machine in a non-exempt facility) and 21 C.F.R. § 1140.14(e) (failure to remove all violative items or bring them into compliance). CTP seeks to impose a \$500 civil money penalty based on three alleged violations of the regulations in a 24-month period. (Compl. ¶ 13.)

Both the cover letter to the complaint and the complaint provided detailed instructions related to filing an answer and requesting an extension of time to file an answer. The letter and complaint stated that failure to file an answer could result in the imposition of a civil money penalty against Respondent. 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, 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 “respondent waives any right to a hearing and to contest the amount of 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. § 1140.14. I also find that CTP’s request to impose a \$500 civil money penalty is permissible. *See* 75 Fed. Reg. 73,951, 73,954 (Nov. 30, 2010) (to be codified at 21 C.F.R. § 17.2).

### **Order**

For the reasons stated above, Respondent is directed to pay a civil money penalty in the amount of \$500. This Order becomes final and binding upon both parties within 30 days of the date of its issuance pursuant to 21 C.F.R. § 17.11(b).

\_\_\_\_\_  
/s/  
Scott Anderson  
Administrative Law Judge