

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

DAL LLC d/b/a Spuds Bar & Grill,

Respondent.

Docket No. C-12-500
FDA Docket No. FDA-2012-H-0312

Decision No. CR2548

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 Phoenix, Arizona that sells tobacco products. CTP conducted inspections of the establishment beginning in April of 2011. During an April 7, 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 fail[ed] to ensure that all violative items [were] removed or [were] brought into compliance with the requirements of 21 C.F.R. Part 1140, as required by 21 C.F.R. § 1140.14(e).

(Compl. ¶ 10.)

On July 7, 2011, CTP issued a warning letter to Respondent specifying the violations that the inspectors observed. The letter warned Respondent that a failure to correct the 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 December 23 and 27, 2011, FDA-commissioned inspectors observed that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes from the vending machine located in Spuds Bar & Grill on December 23, 2011 at approximately 1:10 PM MST." (Compl. ¶ 9.) Further, CTP asserted that: "an employee told the inspector that minors are sometimes permitted to enter the establishment with an adult." *Id.*

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with a complaint on April 11, 2012, via United Parcel Service. CTP charged Respondent with violating the following regulations: 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor); 21 C.F.R. § 1140.14(b)(1) (failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth); 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). *Id.* CTP asked to impose a \$5,000 civil money penalty based on five alleged violations of the regulations in a 36-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. §§ 1140.1(b); 1140.14. I also find that CTP’s request to impose a \$5,000 civil money penalty is permissible. It is less than the maximum penalty allowed under the regulations because CTP could have sought a \$10,000 penalty based on Respondent’s six alleged regulatory violations that occurred within 48 months. *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 \$5,000. 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