

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Country Manor Properties LLC d/b/a Country Store,

Respondent.

Docket No. C-12-766
FDA Docket No. FDA-2012-H-0550

Decision No. CR2579

Date: August 2, 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 Watkins, Colorado that sells tobacco products. Complaint ¶ 2. CTP conducted two inspections of the establishment. Complaint ¶ 8. During the first inspection, on March 29, 2011, the FDA-commissioned inspector observed that Respondent:

[Sold] cigarettes or smokeless tobacco products to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a); [and] fail[ed] to verify by means of photographic identification, containing the bearer's

date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age, as required by 21 C.F.R. § 1140.14(b)(1).

Complaint ¶ 10.

On May 26, 2011, CTP issued a warning letter to Respondent specifying the violations the inspector 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. Complaint ¶ 10.

On June 2, 2011, Jim Hood contacted CTP by telephone and responded to the warning letter on Respondent's behalf. Mr. Hood told CTP that he spoke with his employees about the violations and informed them to cease selling tobacco to minors. Complaint ¶ 11. Mr. Hood stated that he would send a letter further describing Respondent's plans to prevent future tobacco sales to minors; however, CTP never received such a letter. Complaint ¶ 11.

Subsequently, on February 2 and 7, 2012, during a two-part follow-up inspection, the inspector "documented a violation for using a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c)(1)." Complaint ¶ 9. "Specifically, the establishment [had] a self-service display of smokeless tobacco hanging on a wall and [was] open to the general public during business hours. Therefore, this facility does not qualify as one where minors are permitted to enter at any time." Complaint ¶ 9.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on June 6, 2012, via United Parcel Service. CTP charged Respondent with violating 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); and 21 C.F.R. § 1140.16(c)(1) (using a self-service display in a non-exempt facility). Complaint ¶¶ 1, 9, 10. CTP asked the Civil Remedies Division to impose a \$250.00 civil money penalty on Respondent based on two alleged violations of the regulations within a 12-month period. Complaint ¶ 13.

Both the cover letter to the Complaint and the Complaint provided detailed instructions regarding 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 \$250.00 civil money penalty is permissible.¹ *See* 21 C.F.R. § 17.2.

Therefore, Respondent is directed to pay a civil money penalty in the amount of \$250.00. This initial decision becomes final and binding upon both parties within 30 days of the date of its issuance. 21 C.F.R. § 17.11(b).

It is so ordered.

/s/
Scott Anderson
Administrative Law Judge

¹ The CTP Complaint alleges that three regulatory violations occurred within 24 months. Complaint ¶¶ 9-10. However, CTP “requests that a civil money penalty in the amount of \$250.00 be assessed against Respondent for two violations of 21 C.F.R. Part 1140 within a twelve month period.” Complaint ¶ 13. This is less than the maximum penalty allowed under the regulations because CTP could have sought a \$500 penalty. *See* 21 C.F.R. § 17.2.