

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Mannheim Discount Liquors, Inc.
d/b/a Discount Liquors,

Respondent.

Docket No. C-13-538
FDA Docket No. FDA-2013-H-0302

Decision No. CR2777

Date: May 7, 2013

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 (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 in Stone Park, Illinois that sells tobacco products. Complaint ¶ 3. CTP conducted three inspections of the establishment. Complaint ¶ 9. During a September 17, 2011 inspection, an FDA-commissioned inspector observed that Respondent "s[old] tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)." Complaint ¶ 12.

On December 15, 2011, CTP issued a warning letter to Respondent specifying the violation that the inspector observed. Complaint ¶ 12. The letter warned Respondent that a failure to correct the violation could result in the imposition of a civil money penalty and that it was Respondent's responsibility to ensure compliance with the law. Complaint ¶ 12.

On December 28, 2011, and January 3, 2012, CTP received telephone calls from Jerry Marshall, Store Manager, in response to the warning letter and on behalf of Respondent. Complaint ¶ 13. Mr. Marshall stated that "it is the store's policy to request ID from anyone under 27 years old who purchases tobacco products and not to sell tobacco products to persons younger than 18 years of age." Complaint ¶ 13.

On January 25, 2012, CTP acknowledged, in writing, receipt of the establishment's response. Complaint ¶ 13. In the letter, CTP reminded Respondent of its continuing obligation to comply with the Act and its implementing regulations. Complaint ¶ 13.

During another inspection conducted on March 22, 2012, FDA-commissioned inspectors observed Respondent "selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)." Complaint ¶ 10. On July 24, 2012, CTP initiated a civil money penalty action, FDA Docket Number FDA-2012-H-0787, against Respondent. Complaint ¶ 10. On September 7, 2012, an Administrative Law Judge entered a default judgment in the action and found Respondent liable for violations of 21 C.F.R. Part 1140. Complaint ¶ 11; *see also Mannheim Discount Liquors, Inc.*, DAB CR2610 (2012).

During a subsequent inspection on November 7, 2012, at approximately 2:45 p.m., FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes." Complaint ¶ 1.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on March 20, 2013, via United Parcel Service. CTP charged Respondent with violating 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor). Complaint ¶¶ 1, 10, 12. CTP asked the CRD to impose a \$500 civil money penalty based on three alleged violations of the regulations in a 24-month period. Complaint ¶ 15.

The Complaint provided detailed instructions related to filing an answer and requesting an extension of time to file an answer. Complaint ¶¶ 16-20, 22-24. The Complaint stated that a failure to file an answer could result in the imposition of a civil money penalty against Respondent. Complaint ¶ 21. 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 \$500 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 \$500.00. 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