

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

EMAD INC d/b/a Tobacco Sales Saint Paul,

Respondent.

Docket No. C-14-58

FDA Docket No. FDA-2013-H-1269

Decision No. CR3058

Date: January 2, 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 1676 South Robert Street, Saint Paul, Minnesota 55118. Complaint ¶ 2. CTP conducted two inspections of the establishment. Complaint ¶ 8. During an October 15, 2012 inspection, an FDA-commissioned inspector observed the following at Respondent's establishment:

[T]he retailer ha[d] a self-service display of tobacco products that included cigarette rolling machines, cigarette papers, cigarette tubes, pipe tobacco and cans, and bags and pouches of roll-your-own cigarette tobacco, that were all located in a facility where the retailer fails to ensure that no individuals under 18 years of age are present or permitted to enter, at any time. Complaint ¶ 9.

On December 13, 2012, CTP issued a warning letter to Respondent specifying the violation that the inspector observed. The letter warned Respondent that if it failed to correct the violation, civil money penalties could be imposed on it and that it was Respondent's responsibility to ensure compliance with the law. Complaint ¶ 9. Although United Parcel Service (UPS) records indicate that an individual named "WAZ WAZ" received the warning letter on December 14, 2012, the FDA did not receive a response to the warning letter. Complaint ¶ 10. However, in response to another letter from CTP, Ken Waz, General Manager of Respondent's establishment, replied on Respondent's behalf in an April 22, 2013 telephone call. During the call, Mr. Waz "stated that at the time of the inspection pipe tobacco was displayed, [also] that he is aware of all local, state, and federal law[s] regarding the sale of tobacco products[,] and that he diligently ensures that his store complies with the law." Complaint ¶ 10.

During a subsequent two-part inspection conducted on April 15, 2013, and April 16, 2013, FDA-commissioned inspectors documented the following at Respondent's establishment:

[T]he retailer ha[d] a self-service display of tobacco products located in a facility where the retailer fail[ed] to ensure that no individuals under 18 years of age [were] present or permitted to enter, at any time. Self-service displays that included cigarette rolling machines, cigarette papers, cigarette tubes, pipe tobacco and cans, and bags and pouches of roll-your-own cigarette tobacco, were . . . easily accessible to any customer in the store. A person younger than 18 years of age was able to enter the establishment, access the tobacco products contained in the self-service display, and was not asked for ID until a purchase attempt was made. Complaint ¶ 1.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on October 31, 2013, via UPS. CTP charged Respondent with violating 21 C.F.R. § 1140.16(c) (utilizing a self-service display to sell tobacco products in a non-exempt facility). Complaint ¶¶ 1, 9. 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 ¶¶ 13-17, 19-21. The Complaint stated that failure to file an answer could result in the imposition of a civil money penalty against Respondent. Complaint ¶ 18. 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