Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Steve Katsetos d/b/a Steve's Mini Market,

Respondent.

Docket No. C-14-155
FDA Docket No. FDA-2013-H-1369

Decision No. CR3080

Date: January 13, 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 6691 Maddox Boulevard, Chincoteague Island, Virginia 23336. Complaint ¶ 3. CTP conducted two inspections of the establishment. Complaint ¶ 9. During a January 27, 2013 inspection of Respondent's establishment, an FDA-commissioned inspector observed that ". . . a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 2:54 PM ET." Complaint ¶ 10.

On February 21, 2013, 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 ¶ 10.

Steve Katsetsos responded to the warning letter in a February 27, 2013 telephone call. In response to the violation CTP alleged in the warning letter:

> Mr. Katsetos stated that the establishment is strict about checking the identification of tobacco purchasers, and that he will instruct employees to double-check identification to prevent another sale to a minor. Mr. Katsetos also stated that he would speak with every employee about the Warning Letter, and explained that the employee present at the establishment during the sale to the minor was a new hire at the time.

Complaint ¶ 11.

During a subsequent inspection of Respondent's establishment, FDA-commissioned inspectors documented that ". . . a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes on May 22, 2013, at approximately 4:15 PM." Complaint ¶ 1.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on November 14, 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. 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 ¶ 13.

The Complaint provided detailed instructions related to filing an answer and requesting an extension of time to file an answer. Complaint ¶¶ 14-18, 20-22. The Complaint stated that failure to file an answer could result in the imposition of a civil money penalty against Respondent. Complaint ¶ 19. 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, the regulations provide that:

> [T]he 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