## **Department of Health and Human Services**

## DEPARTMENTAL APPEALS BOARD

## **Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

H Garcia Distributors LLC / Hendry A. Garcia d/b/a HG Mini Market,

Respondent.

Docket No. C-14-1073 FDA Docket No. FDA-2014-H-0590

Decision No. CR3292

Date: July 14, 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 152 School Street, Bristol, Connecticut 06010. Complaint ¶ 3. CTP documented violations during two inspections of the establishment. Complaint ¶ 9. During an inspection, an FDA-commissioned inspector observed that:

[A] person younger than 18 years of age was able to purchase a package of Maverick Box 100s cigarettes on August 6, 2013, at approximately 1:26 PM; and . . . the minor's identification was not verified before the sale, as detailed above, on August 6, 2013, at approximately 1:26 PM.

Complaint ¶ 10.

On September 19, 2013, CTP issued a warning letter to Respondent specifying the violations that the inspector observed. The letter warned Respondent that if it failed to correct the violations, civil money penalties could be imposed on it and that it was Respondent's responsibility to ensure compliance with the law. Complaint ¶ 10.

Hendry A. Garcia responded to the warning letter on Respondent's behalf in an October 2, 2013 letter. Mr. Garcia reported that "all employees were instructed to verify the identification of tobacco purchasers who appear to be under 25 years of age." Complaint ¶ 11. In a December 17, 2013 letter, CTP responded to Mr. Garcia and reminded Respondent that federal law requires retailers to verify the photographic identification of tobacco purchasers who appear to be under 27 years of age.

During a subsequent inspection, FDA-commissioned inspectors documented the following at Respondent's establishment:

[A] person younger than 18 years of age was able to purchase a package of USA Gold cigarettes on January 15, 2014, at approximately 9:39 AM; and . . . the minor's identification was not verified before the sale, as detailed above, on January 15, 2014, at approximately 9:39 AM.

Complaint ¶ 1.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on May 14, 2014, via United Parcel Service (UPS). CTP charged Respondent with violating 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor) and 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). Complaint ¶¶ 1, 10. 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 ¶ 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 \$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. 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