

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

v.

Broadway Citgo, Inc.,

Respondent.

Docket No. C-12-439
FDA Docket No. FDA-2012-H-0258

Decision No. CR2543

Date: May 15, 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 Melrose Park, Illinois that sells tobacco products. In 2011, CTP conducted two inspections of the establishment. During a March 24, 2011 inspection, an FDA-commissioned inspector observed that Respondent:

Offer[ed] or caus[ed] to be offered a gift or item to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase, in violation of 21 C.F.R. § 1140.34(b); and fail[ed] to ensure that all violative self-service displays, advertising, labeling and other items that are located in [Respondent's] establishment [were] removed

or [were] brought into compliance with requirements of 21 C.F.R. Part 1140, as required by 21 C.F.R. § 1140.14(e).

(Compl. ¶ 10.)

On June 16, 2011, CTP issued a warning letter to Respondent specifying the violations that the inspectors 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. (Compl. ¶ 10.) The CTP did not receive a response to the warning letter. (Compl. ¶ 11.)

During a two-part inspection on October 31 and November 3, 2011, FDA-commissioned inspectors observed that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes on November 3, 2011 at approximately 7:30 PM CST." (Compl. ¶ 9.) CTP charged Respondent with violating 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor). *Id.* CTP asked to impose a \$250 civil money penalty based on two alleged violations of the regulations in a 12-month period. (Compl. ¶ 13.)

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the complaint on March 16, 2012, via United Parcel Service. Both the cover letter to the complaint and the complaint provided detailed instructions related to 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 civil money penalty is permissible. It is less than the maximum penalty permitted under the regulations because CTP could have sought a \$500 penalty based on Respondent's three regulatory violations that occurred within 24 months. *See* 75 Fed. Reg. 73,951, 73,954 (Nov. 30, 2010) (to be codified at 21 C.F.R. § 17.2).

Order

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

/s/
Scott Anderson
Administrative Law Judge