Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

H and B Gas, Inc. d/b/a Quik Mart / Citgo,

Respondent.

Docket No. T-16-565 FDA Docket No. FDA-2016-H-0925

Decision No. TB699

Date: January 5, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, H and B Gas, Inc. d/b/a Quik Mart / Citgo, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$5,000. Respondent filed an Answer on June 10, 2016. However, it has since failed to comply with my Acknowledgement and Pre-Hearing Order. Therefore, I enter a default judgment against Respondent and assess a civil money penalty in the amount of \$5,000.

I. Procedural History

CTP began this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent's staff impermissibly sold tobacco products to minors and failed to verify that tobacco product purchasers were of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C.

§ 301 et seq., and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. CTP sought a civil money penalty of \$5,000.

On May 31, 2016, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. Respondent filed an Answer on June 10, 2016. I issued an Acknowledgement and Pre-Hearing Order on July 5, 2016 setting out requirements and deadlines for moving this matter to hearing. In that order, the parties were instructed to file pre-hearing exchanges. Initially, CTP's pre-hearing exchange was due on September 26, 2016, and Respondent's was due by October 17, 2016. However, the exchange deadlines were extended to November 25, 2016, and December 16, 2016, respectively, by agreement of the parties.

CTP filed its pre-hearing exchange on November 23, 2016. Respondent failed to file its exchange by the December 16, 2016 deadline. As a result, I issued an Order to Show Cause on December 19, 2016, giving Respondent until January 3, 2017 to file its exchange. Respondent was informed that if it failed to file its exchange, I would conclude that it had abandoned its hearing request and enter a default judgment.

As of the date of this Initial Decision, Respondent has not filed its pre-hearing exchange. Due to this noncompliance with my December 19, 2016 Order, I am striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. §§ 17.35(c) (3), 17.11(a). The sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and I find the failure to comply here sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

II. Default Decision

Striking Respondent's Answer leaves the Complaint unanswered. Therefore, I am required to issue an initial decision by default if the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true and conclude the default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with the orders. 21 C.F.R. § 17.11.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Quik Mart / Citgo, an establishment that sells tobacco products and is located at 19841 Schoolcraft Avenue, Detroit, Michigan 48223. Complaint ¶ 6-7.
- CTP initiated the first civil money penalty action, CRD Docket Number C-15-3196, FDA Docket Number FDA-2015-H-2341, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period. Complaint ¶ 10.
- The previous action concluded when Respondent admitted all of the allegations in the Complaint and paid the agreed upon penalty. Further, "Respondent expressly waived its right to contest such violations in subsequent actions." Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment conducted on November 19, 2015, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes . . . at approximately 7:48 PM. The inspector also documented that "the minor's identification was not verified before the sale" Complaint ¶ 8.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; see 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010); 81 Fed Reg. 28,974, 28975-76 (May 10, 2016). The regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1). The regulations also require retailers to verify, by means of photographic identification containing the purchaser's date of birth, that no tobacco product purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i).

Taking the above alleged facts as true, Respondent had five violations of regulations found at 21 C.F.R. pt. 1140 within a 36-month period. Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on November 6, 2014, March 21, 2015, and November 19, 2015. On March 21, 2015, and November 19, 2015, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R.

§ 1140.14(a)(2)(i). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a civil money penalty of \$5,000, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$5,000 is warranted and so order one imposed.

\langle \langle s\langle Steven T. Kessel Administrative Law Judge