Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

US Gas N Go Inc. d/b/a Food Mart,

Respondent.

Docket No. T-17-1054 FDA Docket No. FDA-2016-H-4167

Decision No. TB1677

Date: July 24, 2017

ORDER GRANTING CTP'S MOTION TO IMPOSE SANCTIONS AND INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, US Gas N Go Inc. d/b/a Food Mart, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$11,002. During the hearing process, Respondent failed to comply with judicial directions regarding CTP's discovery request. I therefore strike Respondent's answer and issue this decision of default judgment.

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, failed to verify that tobacco product purchasers were of sufficient age, and utilized a self-service display in a non-exempt facility, 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 seeks a civil money penalty of \$11,002.

On December 13, 2016, CTP served the Complaint on Respondent by United Parcel Service (UPS), pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent timely filed an answer. On February 7, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO) that contained a provision which set out instructions regarding a party's request for production of documents. That provision states, in part, that a party had until March 16, 2017, to request that the other party provide copies of documents relevant to this case. The order also stated that a party receiving such a request must provide the requested documents no later than 30 days after the request has been made, pursuant to 21 C.F.R. § 17.23(a).

On April 6, 2017, CTP filed a Motion for Leave to Reopen Discovery stating that CTP sent Respondent a Request for Production of Documents on March 9, 2017 via United Parcel Service (UPS). CTP further stated that, "according to UPS records, on March 10, 2017, the receiver refused delivery of the package containing CTP's Request for Production of Documents." CTP requested I reopen discovery for this case, and grant CTP leave to resend its Request for Production of Documents to Respondent. On April 10, 2017, I granted CTP's Motion for Leave to Reopen Discovery and extended the deadline for the parties to serve requests for documents to April 24, 2017.

On April 20, 2017, CTP served its Request for Production of Documents on Respondent. On May 31, 2017, CTP filed a Motion to Impose Sanctions stating. "Respondent has neither produced any of the requested documents, nor contacted Complainant or Counsel for Complainant regarding this matter." CTP further stated that CTP contacted Respondent's establishment and was informed that a new owner is operating the establishment, and Respondent abandoned the establishment and did not leave a forwarding address.

In a "By Direction" letter dated June 1, 2017, Respondent was given until June 15, 2017 to file a response to CTP's Motion to Impose Sanctions. On June 15, 2017, Respondent requested additional time to respond. In a subsequent "By Direction" letter dated June 19, 2017, Respondent was given until July 3, 2017 to file its response. As of the July 3, 2017 deadline, no response has been received in the Civil Remedies Division.

II. Striking Respondent's Answer

Respondent has failed to produce documents in response to CTP's Requests for Production or otherwise comply with my Orders requiring it to participate in the discovery process. Specifically, Respondent has not complied with the deadline set forth in the APHO for responding to any discovery request and failed to respond to the letter issued by my direction on June 19, 2017 soliciting a response to CTP's motion to impose sanctions. Sanction is therefore appropriate in accordance with 21 C.F.R. § 17.35(a). The issue is whether CTP's proposed sanction – striking Respondent's Answer and issuing a default judgment – is the appropriate one. The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and I find here that Respondent's repeated failure to comply is sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

As previously discussed, Respondent has failed to produce any documents, object to any of the requests, or file a motion to protect any documents requested by CTP. The only action taken by Respondent was its June 15, 2017 email request for a two-week extension of time in which to file a response to CTP's Motion for Sanctions. On June 19, 2017, the request for extension was granted and Respondent was given until July 3, 2017 to file a response to the Motion for Sanctions. Yet, Respondent failed to submit a response or produce any documents responsive to CTP's discovery requests.

Respondent has failed to comply with any of my Orders and Directives which afforded the opportunity to come into compliance. Respondent's persistent failure to comply with my Orders and Directives in this matter warrants a severe sanction. Therefore, I am granting CTP's Motion to Impose Sanctions, striking Respondent's Answer, and issue the following default judgment in this case. *See* 21 C.F.R. §§ 17.11(a), 17.35(a)(1), 17.35(c)(3).

III. Default Decision

Striking Respondent's Answer leaves the Complaint unanswered. Therefore, pursuant to 21 C.F.R. § 17.11(a), I am required to "assume the facts alleged in the [C]omplaint to be true" and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

• Respondent owns Food Mart, an establishment that sells tobacco products and is located at 1227 Airport Road, Allentown, Pennsylvania 18109. Complaint ¶¶ 6-7.

- CTP initiated the first civil money penalty action, FDA Docket Number FDA-2015-H-4866, against Respondent for four violations of 21 C.F.R. pt. 1140 within a 24-month period. Complaint ¶ 10.
- The previous action concluded when Respondent "admit[ted] 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 May 21, 2016, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . at approximately 3:47 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, 28,975-76 (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). Also, under 21 C.F.R. § 1140.16(c), no retailer may utilize a self-service display in a facility where a person younger than 18 years of age is present or permitted to enter.

Taking the above alleged facts as true, Respondent had six violations of regulations found at 21 C.F.R. pt. 1140 within a 48-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 April 22, 2015, September 20, 2015, and May 21, 2016. On September 20, 2015 and May 21, 2016, 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). On September 23, 2015, Respondent violated the prohibition against utilizing self-service displays in a facility where persons younger than 18 years of age are permitted to enter. Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a civil money penalty of \$11,002, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$11,002 is warranted and so order one imposed.

/s/ Steven T. Kessel Administrative Law Judge