Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2017-H-3403)

Complainant

v.

Votum LLC. d/b/a Buzz Buy/Valero,

Respondent.

Docket No. T-17-4543

Decision No. TB2312

Date: December 19, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty of \$559 against Respondent, Votum LLC. d/b/a Buzz Buy/Valero, located at 3801 Central Avenue, Hot Springs, Arizona 71913, for three violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a twenty-four month period.

CTP alleges that Buzz Buy/Valero violated the Act by: impermissibly selling cigarettes to minors and failing to verify, by means of photo identification containing a date of birth, that a purchaser was 18 years of age or older.

For the reasons discussed below, I impose a civil money penalty of \$559 against Respondent, Buzz Buy/Valero.

I. Procedural History

CTP began this matter by serving an administrative complaint seeking a \$559 civil money penalty on Respondent Buzz Buy/Valero (Respondent) at 3801 Central Avenue, Hot Springs National Park, Arizona 71913, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent filed a timely Answer on July 14, 2017, in which it admitted to the allegations in the complaint as alleged by CTP. On July 19, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO). The APHO explained that parties may request copies of documents relevant to this case and that the requesting party must serve the request for documents no later than August 17, 2017. The APHO further explained that a party receiving such a request must provide the requested documents no later than 30 days after the request has been made. 21 C.F.R. § 17.23(a).

On August 15, 2017, CTP filed an Unopposed Motion to Extend Deadlines and Notice of Pending Settlement. In its Motion, CTP indicated that the parties agreed to settle the matter and requested that the deadlines set forth in the APHO be extended 30 days. I granted CTP's Motion in an August 16, 2017 Order. That Order established a new deadline of September 18, 2017 for parties to serve requests for documents.

On November 1, 2017, CTP filed a Motion to Compel Discovery. In its motion, CTP stated that on September 18, 2017, CTP served a Request for Production of Documents on Respondent, but had not received a response to its request. On that same date, CTP also filed a Motion to Extend Deadlines. On November 2, 2017, I issued an Order granting CTP's Motion to Compel and ordered Respondent to comply with CTP's Request for Production of Documents by November 20, 2017. In that Order, I stated that "[f]ailure to do so may result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty." In that same Order, I also granted CTP's Motion to Extend Deadlines.

On November 22, 2017, CTP filed a Motion to Impose Sanctions and Issue Default Judgment. In its November 22, 2017 Motion, CTP indicated that Respondent had not complied with my November 2, 2017 Order and requested that Respondent's Answer be struck and that I issue a default judgment. On that same date, CTP also filed a Motion to Extend the pre-hearing exchange deadlines. In a November 24, 2017 letter issued by my direction, Respondent was given until December 7, 2017 to file an objection to CTP's Motion to Impose Sanctions. In a separate Order issued on that date, I extended the parties' pre-hearing exchange deadlines.

To date, Respondent has not filed a response to CTP's Motion to Impose Sanctions.

II. Striking Respondent's Answer

I grant CTP's Motion to Impose Sanctions and strike Respondent's Answer due to a failure to comply with multiple judicial orders and applicable rules.

Pursuant to 21 C.F.R. § 17.35(a), I may sanction a party for:

- (1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;
- (2) Failing to prosecute or defend an action; or
- (3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

Here, Respondent did not comply with the deadline established in my orders on August 16, 2017 and November 2, 2017. Respondent also failed to respond to the November 24, 2017 letter, issued by my direction, soliciting a response to CTP's Motion to Impose Sanctions. Respondent has failed to comply with my orders and the procedures governing this proceeding which constitutes misconduct that has interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a)(1), (a)(3). I, therefore, find that sanctions are appropriate under 21 C.F.R. § 17.35.

The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure. 21 C.F.R. § 17.35(b). I find and conclude that Respondent's misconduct is sufficiently egregious to warrant striking the July 14, 2017 Answer and issuing a decision without further proceeding. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

III. Default Decision

Striking Respondent's Answer leaves the Complaint unanswered. I am, therefore, 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 as alleged in the complaint are true. As such, I conclude that default judgment is merited based on the allegations in the Complaint and the sanctions imposed on Respondent. 21 C.F.R. § 17.11. Specifically:

• At approximately 12:54 p.m. on June 21, 2016, at Respondent's business establishment, 3801 Central Avenue, Hot Springs, Arizona 71913, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age;

- In a warning letter dated June 30, 2016, CTP informed Respondent of the inspector's June 21, 2016 documented violation, and that such action violates federal law. The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action;
- At approximately 2:04 p.m. on March 22, 2017, at Respondent's business establishment, 3801 Central Avenue, Hot Springs, Arizona 71913, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

These facts establish Buzz Buy/Valero's liability 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. § 387f(d); see 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).

Under 21 C.F.R. § 1140.14(a)(1), no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.

A \$559 civil money penalty is permissible for three violations of the regulations under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$559 against Respondent Votum LLC. d/b/a Buzz Buy/Valero. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties 30 days after the date of its issuance.

/s/
Wallace Hubbard
Administrative Law Judge

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On August 8, 2016, the citations to certain tobacco violations changed. For more information see: https://federalregister.gov/a/2016-10685.