

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-6412)

Complainant

v.

Mike's Food and Fuel, Inc.
d/b/a Citgo,

Respondent.

Docket No. T-18-349

Decision No. TB2833

Date: June 22, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Mike's Food and Fuel, Inc. d/b/a Citgo, at 4702 West Gandy Boulevard, Tampa, Florida 33611, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Citgo impermissibly sold covered tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, thereby violating 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. CTP seeks to impose a \$559 civil money penalty against Respondent Citgo.

During the course of the administrative proceedings, Respondent failed to comply with a judicial order and failed to defend its case, which interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a). Accordingly, pursuant to 21 C.F.R. § 17.35(c)(3), I strike Respondent's Answer and issue this decision of default judgment.

I. Procedural History

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on November 14, 2017, CTP served the Complaint on Respondent Citgo by United Parcel Service. On December 13, 2017, Mike Sabbah, on behalf of Respondent, timely answered CTP's Complaint. On December 19, 2017, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for the parties' filings and exchanges and warned that I may impose sanctions if a party failed to comply with any order, including the APHO. APHO ¶¶ 4, 16. In the APHO, I set a deadline of March 12, 2018, for CTP's pre-hearing exchange and April 2, 2018, for Respondent's pre-hearing exchange. APHO ¶ 4. On March 12, 2018, CTP timely filed its pre-hearing exchange. Respondent did not file a pre-hearing exchange by the April 2, 2018 deadline, or at any time thereafter.

On April 9, 2018, I issued an Order Scheduling Pre-Hearing Conference. In this order, I set a pre-hearing conference by telephone for May 23, 2018, at 1:00 PM Eastern Time, to resolve certain issues and schedule a hearing for this case. Respondent did not respond to my Order Scheduling Pre-Hearing Conference indicating that it was unable to appear at the scheduled pre-hearing conference call, nor did Respondent appear at the pre-hearing conference as scheduled.

Accordingly, on May 24, 2018, I issued an Order to Show Cause, in which I provided Respondent until June 6, 2018, to show cause for its failure to appear at the pre-hearing conference. I warned Respondent that:

. . . failure to do so may **result in sanctions**, including striking Respondent's Answer and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty.

(Emphasis in original.)

Subsequently, on May 24, 2018, Mr. Sabbah, on behalf of Respondent, contacted the Civil Remedies Division hotline for assistance. Mr. Sabbah indicated that he did not check his email regularly and stated that he forgot his Departmental Appeals Board Electronic Filing System (DAB E-File) username and password. The attorney assigned to assist me with this case provided Respondent with instructions to remedy, a technical contact, and explained his responsibilities to respond to my Order to Show Cause by June 6, 2018. On June 4, 2018, Respondent filed a response to my Order to Show Cause. In its response, Respondent indicates that it experienced problems logging into its DAB E-File account. As such, Respondent had not seen the April 9, 2018 Order Scheduling Pre-Hearing Conference.

However, this explanation fails. I find it an implausible coincidence that the Respondent called the office almost immediately after I issued the Order to Show Cause, the day after the scheduled pre-hearing conference, to inform our office that it had difficulty logging into the account. Had Respondent experienced difficulty with accessing the file, Respondent should have sought assistance at that point to rectify the problem. It is also noted that the system sends an email notification when an item has been added to the file. Here, in the phone call to the office, Respondent indicated that it did not regularly check the email account associated with Respondent's file.

Although not defined by the regulations, good cause must mean something more than a simple error or omission. Good cause would normally constitute some event or events beyond Respondent's ability to control that acted to prevent Respondent from taking a required action- in this case, appearing at the scheduled pre-hearing conference. Here, Respondent asserts that it had issues logging onto DAB E-File system and thus was precluded from reviewing the April 9, 2018 Order Scheduling Pre-Hearing Conference. However, it was incumbent upon Respondent to timely and promptly resolve any issues with his account, and particularly vital after he received an email notice of a filing.

I do not find that Respondent has shown good cause under any reasonable definition of the term.

II. Striking Respondent's Answer

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.

21 C.F.R. § 17.35(a).

Here, Respondent failed to comply with my April 9, 2018, Order Scheduling Pre-Hearing Conference, when it failed to appear at the May 23, 2018, pre-hearing conference, 21 C.F.R. § 17.35(a)(1); and failed to demonstrate good cause for its failure to appear at the pre-hearing conference 21 C.F.R. § 17.35(a)(2).

I find that Respondent failed to comply with an order and procedure governing this proceeding and failed to defend its action, which has interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a). I conclude that Respondent's

conduct establishes a basis for sanctions pursuant to 21 C.F.R. § 17.35, and that sanctions are warranted.

The harshness of the sanctions I impose must relate to the nature and severity of the misconduct or failure to comply. 21 C.F.R. § 17.35(b). Here, Respondent failed to comply with my order, despite my explicit warning that its failure could result in sanctions and I specified that those sanctions may include “striking Respondent’s Answer and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty.” Respondent also failed to defend its action of failing to appear. I find that Respondent’s actions are sufficient to warrant striking its Answer and issuing a decision by default, without further proceedings. 21 C.F.R. § 17.35(b), (c)(3). Accordingly, I strike Respondent’s Answer, and issue this Initial Decision and Default Judgment, assuming the facts alleged in CTP’s complaint to be true. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

III. Default Decision

Striking Respondent’s answer leaves the Complaint unanswered. Therefore, I am required to issue an initial decision by default, provided that the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Accordingly, I must first 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 (but not its conclusory statements) and I conclude that default judgment is merited based on the allegations of the Complaint. 21 C.F.R. § 17.11. Specifically:

- At approximately 11:13 AM on February 4, 2017, at Respondent’s business establishment, 4702 West Gandy Boulevard, Tampa, Florida 33611, an FDA-commissioned inspector documented Respondent’s staff selling a package of two Swisher Sweets Cherry Dynamite cigars 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;
- In a warning letter dated April 27, 2017, CTP informed Respondent of the inspector’s February 4, 2017 documented violations, and that such actions violate federal law. The letter further warned that Respondent’s failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 12:48 PM on August 3, 2017, at Respondent’s business establishment, 4702 West Gandy Boulevard, Tampa, Florida 33611, an FDA-commissioned inspector documented Respondent’s staff selling a Black & Mild cigar 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 Respondent Citgo'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(b)(1), no retailer may sell covered tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no covered tobacco product purchasers are younger than 18 years of age.

A \$559 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$559 against Respondent Mike's Food and Fuel, Inc. d/b/a Citgo. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/

Wallace Hubbard
Administrative Law Judge