

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-3929)

Complainant

v.

Genesis Citgo Inc.  
d/b/a Citgo,

Respondent.

Docket No. T-17-5025

Decision No. TB2467

Date: February 26, 2018

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Genesis Citgo Inc. d/b/a Citgo, located at 600 West International Speedway Boulevard, Daytona Beach, Florida 32114, 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 cigarettes 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 this administrative proceeding, Respondent has failed to comply with two separate judicial orders and failed to appear at the pre-hearing conference. *See* 21 C.F.R. § 17.35(a). Accordingly, pursuant to 21 C.F.R. §§ 17.35(a)(1), (2), I strike Respondent's Answer and issue this decision of default judgment.

## **I. Procedural History**

CTP began this matter by serving an administrative complaint, seeking a \$559 civil money penalty, on Respondent Genesis Citgo Inc. d/b/a Citgo at 600 West International Speedway Boulevard, Daytona Beach, Florida 32114. Respondent filed an Answer to CTP's complaint on August 3, 2017. The Answer was filed after the July 28, 2017 deadline for answering the complaint, pursuant to 21 C.F.R. § 17.9. On August 8, 2017, a letter issued by my direction was sent to the parties allowing Respondent an opportunity to state the reason for the late filing of its Answer and allowing the Center for Tobacco Products (CTP) to file an objection to the late filed Answer. On August 18, 2017, Respondent filed a response stating that serious health issues led to her forgetting to mail the Answer by the July 28, 2017 deadline; she had placed it in her car, but then became sick and preoccupied over her medical issues. On August 21, 2017, CTP filed its objection to Respondent's late filed Answer. In its opposition, CTP stated that Respondent had not shown that extraordinary circumstances prevented it from filing a timely Answer.

On August 23, 2017, I found good cause for the late filing of Respondent's Answer and issued an Acknowledgement and Prehearing Order (APHO). On November 13, 2017, CTP timely filed its pre-hearing exchange. Respondent did not file a pre-hearing exchange.

On December 12, 2017, I issued an Order Scheduling Pre-Hearing Conference, setting a pre-hearing conference by telephone for December 28, 2017, at 11:00 a.m. Eastern Time. On December 13, 2017, CTP filed a Motion to Compel Discovery, requesting that I issue an order compelling Respondent to produce documents responsive to its discovery request. On the same date, CTP also filed a Motion to Reschedule Pre-Hearing Conference stating that it needed sufficient time to review the documents requested in its Motion to Compel and Request for Production of Documents. On December 20, 2017, I issued an Order denying both CTP's Motion to Compel Discovery and its Motion to Reschedule Pre-Hearing Conference. Given the fact that CTP's motion was not timely filed, and was therefore denied, no basis remained for rescheduling the pre-hearing conference.

On December 28, 2017, I convened the previously scheduled Pre-Hearing Conference by telephone. CTP's counsel joined the pre-hearing conference, but Respondent failed to appear. On December 29, 2017, I issued an Order to Show Cause, allowing Respondent until January 12, 2018 to provide an explanation for failure to appear at the pre-hearing conference. My Order to Show Cause warned Respondent 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 pursuant to 21 C.F.R. § 17.35(a)." To date, Respondent has not responded to my Order to Show Cause.

## **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 December 12, 2017, Order Scheduling Pre-Hearing Conference when it failed to appear at the December 28, 2017, pre-hearing conference; and
- Comply with my December 29, 2017, Order to Show Cause when it failed to show cause for its failure to appear at the pre-hearing conference.

I find that Respondent failed to comply with two judicial orders and failed to defend its actions, 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 two orders, despite being warned that failure to comply could result in sanctions including issuance of an Initial Decision and Default Judgment, and failed to appear for a previously scheduled pre-hearing conference. I find that Respondent's failure to comply is sufficient to warrant striking its Answer and issuing a decision by default, without further proceedings. 21 C.F.R. §§ 17.35(a), (b). 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(a), 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 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:

- At approximately 2:30 p.m. on May 15, 2016, at Respondent's business establishment, 600 West International Speedway Boulevard, Daytona Beach, Florida 32114, an FDA-commissioned inspector observed Respondent's staff selling a package of Newport Non-Menthol Box 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;
- In a warning letter dated May 26, 2016, CTP informed Respondent of the inspector's May 15, 2016 observations, 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 7:16 p.m. on April 3, 2017, at Respondent's business establishment, 600 West International Speedway Boulevard, Daytona Beach, Florida 32114, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box 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 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). Under 21 C.F.R. § 1140.14(a)(1)<sup>1</sup>, 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.

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<sup>1</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

**Order**

For these reasons, I enter default judgment in the amount of \$559 against Respondent Genesis Citgo 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/\_\_\_\_\_  
Catherine Ravinski  
Administrative Law Judge