

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-4558)

Complainant

v.

Sylvester J. Colligan  
d/b/a Colligans Groceries,

Respondent.

Docket No. T-17-5589

Decision No. TB2439

Date: February 12, 2018

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Sylvester J. Colligan d/b/a Colligans Groceries, at 114 Fontenot Road, Opelousas, Louisiana 70570, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Colligans Groceries impermissibly sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that a purchaser was 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 Colligans Groceries.

During the course of the administrative proceedings in this case, Respondent has failed to comply with two separate judicial orders, failed to comply with a procedure governing this proceeding, and did not respond to two judicial directions. 21 C.F.R. § 17.35(a)(1).

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 August 3, 2017, CTP served the Complaint on Respondent Colligans Groceries by United Parcel Service. Respondent timely answered CTP's Complaint by letter dated August 8, 2017. In its answer, Respondent denied the allegations made in the Complaint and took exception to the penalty. Respondent stated that it reviewed store security camera footage and did not see evidence of the purported violations. Respondent asserted that the descriptions of the sales clerks did not match that of its staff. Respondent anticipated that, had the inspector noted a violation, the inspector would have notified Respondent immediately. Respondent explained that it was skeptical of the procedures and processes followed for the inspections and notices. Respondent stated that it surmised that the Warning Letter was part of a scam and that only upon receipt of this Complaint was Respondent given an opportunity to file a form challenging the results of the inspection. On August 23, 2018, Respondent sent a completed form Answer, denying the allegations in the Complaint, objecting to the penalty, and reiterating its prior assertions.

On August 15, 2017, I issued an Acknowledgement and Pre-Hearing Order (APHO), in which I acknowledged Respondent's Answer and request for hearing. 21 C.F.R. § 17.9(a). Also in the APHO, I set deadlines for the parties' filings and exchanges, including a schedule for discovery. I directed that a party receiving a discovery request must provide the requested documents within 30 days of the request or request a protective order from doing so within 10 days of the request. APHO at ¶ 12; 21 C.F.R. § 17.23(a), (d).

In accordance with the deadlines set in the APHO, CTP served Respondent with its Request for Production of Documents on September 18, 2017. Respondent did not produce the requested documents or seek a protective order. On October 24, 2017, CTP filed a Motion to Compel Discovery asserting that Respondent had not responded to its discovery request. In an October 26, 2017, letter issued at my direction, Respondent was notified that it had until November 9, 2017, to file a response to CTP's Motion to Compel Discovery, citing 21 C.F.R. § 17.32(c). Respondent did not file a response.

On November 13, 2017, CTP filed a Status Report indicating that it had not received a reply or documents in response to its Request for Production of Documents. Accordingly, on November 14, 2017, I issued an order granting CTP's motion (Order to Compel Discovery) and I ordered Respondent to comply with CTP's Request for Production of Documents by November 27, 2017. In this order, I explicitly warned Respondent:

Failure to comply **will result in sanctions** which may include issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty. 21 C.F.R. § 17.35.

Order to Compel Discovery (emphasis in original).

On December 6, 2017, CTP filed a Motion to Impose Sanctions and Issue Default Judgment. CTP advised that Respondent had not complied with my Order to Compel Discovery and asked that I strike Respondent's Answer as a sanction and issue default judgment in its favor. In a December 12, 2017, letter issued at my direction, Respondent was informed that it had until December 21, 2017, to file a response to CTP's Motion for Sanctions, citing 21 C.F.R. § 17.32(c). Again, Respondent did not file a response.

## II. Striking Respondent's Answer

Respondent failed to:

- Comply with a judicial order when it failed to respond to CTP's Request for Production of Documents within 30 days in violation of my APHO;
- Comply with the procedure governing the proceeding when it failed to respond to CTP's Request for Production of Documents within 30 days in violation of 21 C.F.R. § 17.23(a); and
- Comply with a second judicial order when it failed to produce the requested documents by November 27, 2017, in violation of my November 14, 2017, Order to Compel Discovery.

Additionally, Respondent was provided opportunities to file responses to CTP's Motion to Compel Discovery and CTP's Motion to Impose Sanctions, in letters issued at my direction on October 26, 2017, and December 12, 2017, respectively. Respondent did not avail itself of either opportunity.

I find that Respondent has failed to comply with two judicial orders, a procedure governing the proceeding, and did not respond to two judicial directions. I find that Respondent's conduct constitutes a basis for sanctions pursuant to 21 C.F.R. § 17.35(a). I therefore grant CTP's Motion to Impose Sanctions.

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 repeatedly failed to comply with my orders, despite my explicit warning that its failure "will result in sanctions," and specified that those sanctions "may include issuance of an Initial

Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty.” I find that Respondent’s repeated 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(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 11:55 AM on October 9, 2015, at Respondent’s business establishment, 114 Fontenot Road, Opelousas, Louisiana 70570, an FDA-commissioned inspector documented Respondent’s staff selling a package of Kool Menthol Filter Kings Box cigarettes to a person younger than 18 years of age;
- In a warning letter dated October 29, 2015, CTP informed Respondent of the inspector’s October 9, 2015 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 12:05 PM on June 6, 2017, at Respondent’s business establishment, 114 Fontenot Road, Opelousas, Louisiana 70570, an FDA-commissioned inspector documented Respondent’s staff selling a package of Kool Menthol Filter Kings 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 Colligans Groceries’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),<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.

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 Sylvester J. Colligan d/b/a Colligans Groceries. 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.

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/s/  
Catherine Ravinski  
Administrative Law Judge

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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>.