

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

Oasis Express, Inc.  
d/b/a Oasis Express,

Respondent.

Docket No. T-19-71  
FDA Docket No. FDA-2018-H-3794

Decision No. TB4068

Date: July 11, 2019

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Oasis Express, Inc. d/b/a Oasis Express, at 1401 Pinehurst Road, Dunedin, Florida 34698, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. CTP seeks to impose an \$11,182 civil money penalty against Respondent for a total of six violations within a 48-month period. The complaint alleges that a previous civil money penalty action concluded after Respondent admitted to five 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. The complaint also alleges that Respondent subsequently sold a regulated tobacco product to a minor thereby further violating the Act and its implementing regulations.

Respondent timely answered CTP's complaint; however during the course of these administrative proceedings, Respondent failed to comply with orders and procedures

governing this proceeding and failed to defend its actions, 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, issue this decision of default judgment, and assess a civil money penalty of \$11,182 against Respondent.

## I. Procedural History

On October 10, 2018, CTP served the complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. Respondent timely filed an Answer dated December 3, 2018, denying the allegations in the complaint. On December 11, 2018, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for filings, including a schedule for discovery. I directed that a party receiving a Request for Production of Documents must provide the requested documents within 30 days of the request. APHO ¶ 12; *see* 21 C.F.R. § 17.23(a).

On February 7, 2019, CTP filed a Motion to Compel Discovery asserting that Respondent did not provide any of the requested documents as required by my APHO and regulations. By Order of February 8, 2019, I informed Respondent of its deadline to file a response to CTP's Motion to Compel Discovery, and warned that if Respondent failed to respond, "I may grant CTP's motion in its entirety." *See also* 21 C.F.R. § 17.32(c); APHO ¶ 19. Respondent did not respond.

On April 23, 2019, I issued an Amended Order to Compel Discovery<sup>1</sup> in which I granted CTP's motion and ordered Respondent to produce documents responsive to CTP's Request for Production of Documents by May 10, 2019. I warned Respondent that:

[F]ailure to comply may **result in sanctions**, which may include striking its filings and issuing 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.

April 23, 2019, Amended Order to Compel Discovery (emphasis in original).

On May 16, 2019, CTP filed a Renewed Motion to Impose Sanctions. CTP advised that Respondent did not produce responsive documents in compliance with my Amended Order to Compel Discovery. By Order of May 17, 2019, I informed Respondent that it had until May 31, 2019, to file a response to CTP's Motion to Impose Sanctions and I warned Respondent that if it failed to file a response, I may grant CTP's motion. On May 17, 2019, a letter was also issued at my direction reiterating the deadline for

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<sup>1</sup> The Amended Order to Compel Discovery cured a defect of service in the initial Order to Compel Discovery dated February 26, 2019.

Respondent to file a response to CTP's motion and again warned Respondent that if it failed to file a response, I may "**grant CTP's Renewed Motion to Impose Sanctions in its entirety.**" May 17, 2019, Letter By Direction of the Administrative Law Judge (emphasis in original). The letter specified that the consequences of such a ruling may include "finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty." *Id.*

## II. Striking Respondent's Answer

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).

Respondent failed to comply with the following orders and procedures governing this proceeding:

- Respondent failed to comply with 21 C.F.R. § 17.23(a) and paragraph 12 of my APHO, when Respondent failed to respond to CTP's Request for Production of Documents within 30 days; and
- Respondent failed to comply with my April 23, 2019 Amended Order to Compel Discovery, when it failed to produce documents responsive to CTP's Request for Production of Documents by May 10, 2019.

Respondent also failed to defend its action despite my February 8 and May 17, 2019 orders and May 17, 2019 letter informing Respondent of such opportunities and warning of consequences.

I find that Respondent failed to comply with orders and procedures governing this proceeding, failed to defend its case, and, as a result, interfered with the speedy, orderly, or fair conduct of this proceeding. 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 of my orders, despite my explicit warnings that its failure could result in sanctions. I specified that those sanctions "may include striking its filings and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed

in the Complaint and imposing a civil money penalty.” April 23, 2019, Amended Order to Compel Discovery. Respondent also failed to defend its actions, despite my orders and directive expressly reminding Respondent of the opportunity. Respondent’s repeated misconduct interfered with the speedy, orderly, or fair conduct of this proceeding.

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. 21 C.F.R. § 17.35(c)(3).

### **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). Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint 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:

- On December 18, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-18-681, FDA Docket Number FDA-2017-H-6894, against Respondent for violations of 21 C.F.R. pt. 1140, five<sup>2</sup> of which occurred within the 48-month period relevant in the current complaint. CTP alleged those violations to have occurred at Respondent’s business establishment located at 1401 Pinehurst Road, Dunedin, Florida 34698, on November 21, 2014, May 21, 2016, March 13, 2017, and December 5, 2017;
- The previous action concluded when Respondent admitted the allegations contained in the complaint issued by CTP, and paid the agreed upon monetary penalty in settlement of that claim. Further, “Respondent expressly waived its right to contest such violations in subsequent actions”;
- At approximately 2:49 PM on July 22, 2018, at Respondent’s business establishment located at 1401 Pinehurst Road, Dunedin, Florida 34698, an

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<sup>2</sup> Two violations were identified on November 21, 2014, two on May 21, 2016, one on March 13, 2017, and one on December 5, 2017. In accordance with FDA policy, CTP counted the violations identified during the initial inspection as a single violation and all violations identified during subsequent inspections individually. *See also* CRD Docket Number T-17-5099, FDA Docket Number FDA-2017-H-4013; CRD Docket Number T-17-1060, FDA Docket Number FDA-2016-H-4183.

