

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Aloke and Anand Food Corporation
d/b/a 4 Brothers Food Store,

Respondent.

Docket No. T-18-3245
FDA Docket No. FDA-2018-H-3142

Decision No. TB3579

Date: March 12, 2019

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Aloke and Anand Food Corporation d/b/a 4 Brothers Food Store, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$5,591. CTP began this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent's staff impermissibly sold covered tobacco products to minors and failed to verify that purchasers were of sufficient age, 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 a civil money penalty of \$5,591 for at least five violations within a 36-month period.

During the course of these administrative proceedings, Respondent failed to comply with orders and procedures governing this proceeding and failed to defend this action, 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

On August 15, 2018, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. Respondent timely answered CTP's Complaint on September 10, 2018. On September 14, 2018, I issued an Acknowledgement and Pre-Hearing Order (APHO) that 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. APHO ¶ 12; *see* 21 C.F.R. § 17.23(a). I warned:

I may impose sanctions including, but not limited to, dismissal of the complaint or answer, if a party fails to comply with any order (including this order), fails to prosecute or defend its case, or engages in misconduct that interferes with the speedy, orderly, or fair conduct of the hearing. 21 C.F.R. § 17.35.

APHO ¶ 16.

In accordance with the deadlines set forth in the APHO, CTP served Respondent with its Request for Production of Documents on September 27, 2018. On November 7, 2018, CTP filed a Motion to Compel Discovery asserting that Respondent had not responded to its discovery request. On November 26, 2018, a letter issued by my direction advised Respondent that it had until December 11, 2018, to file a response to CTP's Motion to Compel Discovery. *See also* 21 C.F.R. § 17.32(c); APHO ¶ 19. Respondent failed to submit a response to CTP's Motion to Compel or the November 26, 2018 letter, or otherwise comply with CTP's Request for Production of Documents.

On January 2, 2019, I issued an Order granting CTP's Motion to Compel Discovery and ordering Respondent to produce responsive documents to CTP's Request for Production of Documents by January 18, 2019. I warned:

Failure to [comply] 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.

January 2, 2019, Order, at 1-2. In the same Order, I also extended the parties' pre-hearing exchange deadlines. *Id.* at 2.

On January 28, 2019, CTP filed a Status Report and Motion to Impose Sanctions. CTP advised that Respondent had not complied with my January 2, 2019 Order requiring

Respondent to produce documents responsive to CTP's Request for Production of Documents by January 18, 2019. CTP argued that sanctions against Respondent for its repeated non-compliance are an appropriate remedy. Specifically, CTP asked that I strike Respondent's Answer as a sanction and issue an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty.

On January 31, 2019, a letter issued by my direction informed Respondent that it had until February 15, 2019, to file a response to CTP's Motion to Impose Sanctions. To date, Respondent has not filed a response to CTP's Motion to Impose Sanctions or the January 31, 2019 letter.

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 January 2, 2019, Order, when it failed to submit documents responsive to CTP's Request for Production of Documents by January 18, 2019.

Respondent failed to defend its action despite the following opportunities:

- By letter issued by my direction on November 26, 2018, Respondent was informed that it had until December 11, 2018, to file a response to CTP's Motion to Compel Discovery. Respondent failed to respond to CTP's Motion to Compel or otherwise respond to the November 26, 2018 letter; and

- By letter issued by my direction on January 31, 2019, Respondent was informed that it had until February 15, 2019, to file a response to CTP's Motion to Impose Sanctions. Respondent failed to respond to CTP's Motion to Impose Sanctions or otherwise respond to the January 31, 2019 letter.

I find that Respondent failed to comply with orders and procedures governing this proceeding, failed to defend this action, and, as a result, interfered with the speedy, orderly, and 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 Answer and "issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty." APHO ¶ 16; January 2, 2019, Order, at 1-2. Respondent also failed to defend this action, despite express reminders of the opportunity through letters issued by my direction. 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, 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).

II. 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 [C]omplaint 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:

- Respondent owns 4 Brothers Food Store, an establishment that sells tobacco products and is located at 2008 Northeast 164th Street, North Miami, Florida 33162. Complaint ¶¶ 7-8.
- On March 30, 2018, CTP initiated the first civil money penalty action, CRD Docket Number T-18-1787, FDA Docket Number FDA-2018-H-1309, against Respondent for violations of 21 C.F.R. pt. 1140. Complaint ¶ 11.
- The previous action concluded when Respondent “admitted all of the allegations in the Complaint and paid the agreed upon penalty.” Specifically, Respondent admitted to two violations of the regulations on July 13, 2017, and two on March 14, 2018.¹ Further, “Respondent expressly waived its right to contest such violations in subsequent actions.” Complaint ¶¶ 11-12.
- During a subsequent inspection of Respondent’s establishment conducted on June 27, 2018, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a Black & Mild cigar . . . at approximately 12:07 PM.” The inspector also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 9.

These facts establish that Respondent is liable 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. § 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). The regulations prohibit the sale of covered tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). The regulations also require retailers to verify, by means of photographic identification containing the purchaser’s date of birth, that no covered tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(2)(i).

¹ Customarily, CTP counts all violations documented during each inspection individually, except all violations documented during the initial inspection are only counted as one violation. *Orton Motor, Inc. d/b/a Orton’s Bagley v. U.S. Dep’t of Health & Human Serv.*, 884 F.3d 1205 (D.C. Cir. 2018). In this case, CTP counts only three prior violations in calculating the total number of violations that fall within the current 36-month period at issue.

Taking the above-alleged facts as true, Respondent had at least five violations of regulations found at 21 C.F.R. pt. 1140 within a 36-month period. Respondent violated the prohibition against selling covered tobacco products to persons younger than 18 years of age on July 13, 2017, March 14, 2018, and June 27, 2018. 21 C.F.R. § 1140.14(b)(1). On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no covered tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(2)(i). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a civil money penalty of \$5,591, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$5,591 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge