

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Christal Investments III, Inc.
d/b/a Le Jeune Food Store,

Respondent.

Docket No. T-17-351
FDA Docket No. FDA-2016-H-3469

Decision No. TB1429

Date: June 8, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Christal Investments III, Inc. d/b/a Le Jeune Food Store, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$2,200. During the hearing process, Respondent failed to comply with judicial directions regarding CTP's discovery request. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

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 tobacco products to minors and failed to verify that tobacco product 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, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$2,200.

On November 1, 2016, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

On December 28, 2016, Respondent timely filed an answer. On January 3, 2017, I issued an Acknowledgment and Pre-hearing Order that contained a provision that set out instructions regarding a party's request for production of documents. That provision states, in part, that a party had until February 9, 2017, to request that the other party provide copies of documents relevant to this case. The order also stated that a party receiving such a request must provide the requested documents no later than 30 days after the request has been made, pursuant to 21 C.F.R. § 17.23(a).

On February 9, 2017, CTP served its Request for Production of Documents on Respondent. On March 20, 2017, CTP filed a Motion to Compel Discovery stating it had not received a response from Respondent regarding its Request for Production of Documents. In a March 21, 2017 letter issued by my direction, Respondent was given until March 31, 2017 to file a response to CTP's Motion to Compel Discovery.

Respondent failed to respond to my March 21, 2017 letter. Therefore, on April 12, 2017, I granted CTP's Motion to Compel Discovery, and ordered Respondent to comply with CTP's discovery request by April 27, 2017. Respondent was warned that failure to comply with CTP's discovery request could 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.

On May 16, 2017, CTP filed a Motion to Impose Sanctions indicating that Respondent had not complied with my April 12, 2017 order. In a May 17, 2017 letter issued by my direction, Respondent was given until June 1, 2017 to file a response to CTP's Motion to Impose Sanctions. To date, Respondent has not responded to CTP's motion or produced the requested documents as ordered.

II. Striking Respondent's Answer

Pursuant to 21 C.F.R. § 17.35, I am granting CTP's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with judicial directions. Specifically, Respondent has not complied with the deadline set forth in the APHO for responding to

any discovery request, the order granting CTP's motion to compel discovery issued on April 12, 2017, and finally the letter issued by my direction on May 17, 2017 soliciting a response to CTP's motion to impose sanctions. The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and I find here that Respondent's repeated failure to comply is sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

III. Default Decision

Striking Respondent's answer leaves the complaint unanswered. 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 Le Jeune Food Store, an establishment that sells tobacco products and is located at 298 Northwest 42nd Avenue, Miami, Florida 33126. Complaint ¶¶ 6-7.
- CTP initiated the first civil money penalty action, FDA Docket Number FDA-2015-H-4605, against Respondent for three¹ violations of 21 C.F.R. pt. 1140 within a 24-month period. Complaint ¶ 10.
- The previous action concluded when Respondent "admit[ted] all of the allegations in the Complaint and [paid] the agreed upon penalty." Further, "Respondent expressly waived its right to contest such violations in subsequent actions." Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment conducted on April 12, 2016, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 7:46 PM." Complaint ¶ 8.

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

¹Two violations were documented on March 18, 2015, and two on August 30, 2015. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

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 tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1). The regulations also require retailers to verify, by means of photographic identification containing the purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i).

Taking the above alleged facts as true, Respondent had four violations of regulations found at 21 C.F.R. pt. 1140 within a 24-month period. Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on March 18, 2015, August 30, 2015, and April 12, 2016. On March 18, 2015 and August 30, 2015, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a civil money penalty of \$2,200, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$2,200 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge