

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-6965)

Complainant

v.

Ise Grocery, Inc.
d/b/a Samoset Grocery,

Respondent.

Docket No. T-18-731

Decision No. TB2840

Date: June 26, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Ise Grocery, Inc. d/b/a Samoset Grocery, located at 3011 15th Street East, Bradenton, Florida 34208, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Samoset Grocery impermissibly sold covered tobacco products to minors, 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 \$279 civil money penalty against Respondent Samoset Grocery.

During the course of this administrative proceeding, Respondent has failed to comply with two separate judicial orders and failed to prosecute its case. *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 \$279 civil money penalty, on Respondent Ise Grocery, Inc. d/b/a Samoset Grocery on December 27, 2017. Respondent filed an Answer to CTP's complaint on January 11, 2018. I issued an Acknowledgment and Prehearing Order (APHO) on January 11, 2018, that set deadlines for parties' submissions, including the February 13, 2018 deadline to request that the opposing party provide copies of documents relevant to this case. Additionally, the APHO stated that a party receiving such a request must provide the requested documents no later than 30 days after the request. On February 6, 2018, Respondent served CTP with its request for documents, seeking a copy of the driver's license used by the alleged minor who purchased tobacco products.

On February 14, 2018, CTP filed a Motion for a Protective Order, seeking to limit discovery. On March 8, 2018, CTP filed a Memorandum of Law in Support of Complainant's Motion for a Protective Order. In a March 8, 2018 letter issued by my direction, Respondent was given until March 23, 2018 to file a response to CTP's Motion for a Protective Order. Respondent did not file a response to CTP's Motion for a Protective Order.

On March 26, 2018, CTP filed a Motion to Compel Discovery, indicating that Respondent did not respond to its request for documents within the time limit. *See* 21 C.F.R. § 17.23(a). On the same date, CTP also filed a Motion to Extend Deadlines requesting that all pre-hearing exchange deadlines be extended for 30 days. In a March 26, 2018 letter issued by my direction, Respondent was given until April 10, 2018, to object to CTP's Motion to Compel Discovery. Respondent did not file an objection to CTP's motion.

On April 12, 2018, I granted CTP's Motion for a Protective Order and ordered CTP to serve redacted copies of the minors' photographic identification on Respondent. On the same date, I granted CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines. The Order Granting CTP's Motion to Compel allowed Respondent until April 26, 2018 to comply with CTP's discovery request. CTP subsequently filed a Status Report and Motion to Impose Sanctions, on May 3, 2018, indicating that Respondent had not responded to its Request for Production of Documents. In a May 3, 2018 letter issued by my direction, Respondent was allowed until May 18, 2018 to respond to CTP's Motion to Impose Sanctions. To date, Respondent has not filed a response.

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.

Here, Respondent failed to:

- Comply with my January 11, 2018 Acknowledgment and Pre-Hearing Order that set deadlines for parties' submissions, including the February 13, 2018 deadline to request that the opposing party provide copies of documents relevant to this case;
- Comply with my April 12, 2018 Order Granting CTP's Motion to Compel; and
- Prosecute or defend its case.

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 having been warned that failure to comply could result in sanctions including issuance of an Initial Decision and Default Judgment. Additionally, Respondent has not communicated with the Court since February 6, 2018. I note that Respondent did not take the opportunity to respond to two separate letters issued by my direction on March 26, 2018, and May 3, 2018. 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(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 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 6:33 p.m. on February 2, 2017, at Respondent's business establishment, 3011 15th Street East, Bradenton, Florida 34208, an FDA-commissioned inspector documented Respondent's staff selling a Black & Mild cigar to a person younger than 18 years of age.;
- In a warning letter dated February 16, 2017, CTP informed Respondent of the inspector's February 2, 2017 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 6:33 p.m. on December 8, 2017, at Respondent's business establishment, 3011 15th Street East, Bradenton, Florida 34208, an FDA-commissioned inspector documented Respondent's staff selling a package of two Game Garcia y Vega Grape cigars to a person younger than 18 years of age.

These facts establish Respondent Samoset Grocery'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(b)(1), no retailer may sell covered tobacco products to any person younger than 18 years of age.

Order

For these reasons, I enter default judgment in the amount of \$279 against Respondent Ise Grocery, Inc. d/b/a Samoset Grocery. 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/

Margaret G. Brakebusch
Administrative Law Judge