

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-0308)

Complainant

v.

Hinsdale Trading Co.
d/b/a Hinsdale Trading Company,

Respondent.

Docket No. T-17-1735

Decision No. TB1696

Date: July 28, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Hinsdale Trading Co. d/b/a Hinsdale Trading Company, located at 371 Old Dalton Road, Hinsdale, Massachusetts 01235, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Hinsdale Trading Company impermissibly sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 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 \$550 civil money penalty against Respondent Hinsdale Trading Company. During the hearing process, Respondent has failed to comply with multiple 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 matter by serving an administrative complaint, seeking a \$550 civil money penalty, on Respondent Hinsdale Trading Company. Respondent filed an answer to CTP's complaint on March 1, 2017. I issued an Acknowledgement and Prehearing Order (APHO) on March 2, 2017, that set deadlines for parties' submissions, including the April 3, 2017, 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. CTP served Respondent with its request for documents on April 3, 2017.

On May 11, 2017, CTP filed a Motion to Compel Discovery indicating that Respondent did not respond to its request within the time limit. *See* 21 C.F.R. § 17.23(a). In a letter issued by my direction, Respondent was given until May 26, 2017, to object to CTP's motion. Respondent did not file an objection.

In a May 30, 2017, Order, I granted CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines. The Order allowed Respondent until June 14, 2017 to comply with CTP's discovery request. In granting CTP's Motion to Compel Discovery, I explained 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. CTP subsequently filed a Motion to Impose Sanctions on June 15, 2017, indicating that Respondent did not comply with the Order Granting CTP's Motion to Compel. In a June 16, 2017, letter issued by my direction, Respondent was given until July 6, 2017, to object to CTP's motion. A second by direction letter was issued on July 14, 2017, after it was realized that the address on the July 6, 2017, letter listed the wrong zip code. As a result, Respondent was given an extension until July 24, 2017, to file an objection to CTP's Motion to Impose Sanctions. As of the date of this Decision, a response has not been received.

It should be noted that Respondent was given electronic access to the file on or before March 1, 2017. It also appears from DAB E-File that a vast majority of the documents were also mailed to Respondent. As a result, it is unclear why Respondent has failed to comply with my Orders. In my letter of July 14, 2017, I specifically requested that the parties confirm receipt of the letter. Respondent failed to comply with this directive. This letter was filed electronically and mailed to the Respondent. As of the date of this decision, the mailed copy of the letter has not been returned as undelivered nor has there been notice that the electronic copy was not successfully delivered to the Respondent. Accordingly, there is no indication that the Respondent did not receive either or both copies of the July 14, 2017, letter.

II. Striking Respondent's Answer

As noted above, on May 11, 2017, CTP filed a Motion to Compel Discovery. Respondent failed to file a response. On May 30, 2017, I granted Respondent's Motion and gave Respondent until June 13, 2017 to produce responses to the discovery request. On June 15, 2017, CTP filed a Motion to Impose Sanctions. In its Motion for Sanctions, CTP stated that "Respondent has neither produced any of the requested documents, nor contacted Complainant or Counsel for Complainant regarding this matter." On June 16, 2017, a letter was issued under my direction giving Respondent until July 3, 2017 to file a response to the Motion for Sanctions. The letter was filed electronically and mailed to Respondent. On July 14, 2017, a second letter issued, giving Respondent an opportunity to respond to CTP's motion for Sanctions. As of the date of the decision, Respondent has not filed a response to either letter.

Due to noncompliance with my Acknowledgement and Pre-Hearing Order (APHO), my Order granting CTP's Motion to Compel, and my by direction letters ordering a response to CTP's motion for sanctions, I am striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. § 17.35(a)(1), 17.35(c) (3), 17.11(a). 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 the failure to comply here 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. 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 3:30 p.m. on April 28, 2016, at Respondent's business establishment, 371 Old Dalton Road, Hinsdale, Massachusetts 01235, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport 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;

- In a warning letter dated May 26, 2016, CTP informed Respondent of the inspector's April 28, 2016 documented violations, and that such actions violate federal law. The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 10:52 a.m. on July 8, 2016, at Respondent's business establishment, 371 Old Dalton Road, Hinsdale, Massachusetts 01235, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport 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 Hinsdale Trading Company'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)¹, 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 \$550 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$550 against Respondent Hinsdale Trading Co. d/b/a Hinsdale Trading Company. 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

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.