

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-2572)

Complainant

v.

Caldwell Confectionery LLC,

Respondent.

Docket No. T-16-1822

Decision No. TB904

Date: March 2, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Caldwell Confectionery LLC, located at 420 Bloomfield Avenue, Caldwell, New Jersey 07006, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Caldwell Confectionery LLC 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. The complaint likewise alleges that Respondent Caldwell Confectionery LLC previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,501 civil money penalty against Respondent Caldwell Confectionery. During the hearing process, Respondent has failed to comply with three separate 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 \$5,501 civil money penalty, on Respondent Caldwell Confectionery LLC. Respondent filed an answer to CTP's complaint on October 11, 2016. I issued an Acknowledgement and Prehearing Order (APHO) on October 14, 2016, that set deadlines for parties' submissions, including the November 23, 2016 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 November 23, 2016.

On January 4, 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 January 19, 2017, to object to CTP's motion. Respondent did not file an objection to CTP's motion.

In a January 25, 2017, Order, I granted CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines. The Order allowed Respondent until February 7, 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 February 8, 2017, indicating that Respondent did not comply with the Order Granting CTP's Motion to Compel. In a February 8, 2017, letter issued by my direction, Respondent was given until February 24, 2017, to object to CTP's motion. As of the date of this Initial Decision, Respondent has not objected to CTP's Motion to Impose Sanctions.

II. Striking Respondent's Answer

On February 8, 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." As previously noted, Respondent has failed to file a response to CTP's motion.

Due to noncompliance with my Acknowledgement and Pre-Hearing Order (APHO), my Order granting CTP's Motion to Compel, and my by direction letter ordering production of documents, 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:

- On August 17, 2015, CTP initiated a previous civil money penalty action, CRD Docket Number C-15-3569, FDA Docket Number FDA-2015-H-2745, against Respondent for three¹ violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred at Respondent's business establishment, 420 Bloomfield Avenue, Caldwell, New Jersey 07006, on November 8, 2014, and April 6, 2015;
- The previous action concluded when Respondent admitted 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;
- At approximately 10:13 a.m. on February 6, 2016, at Respondent's business establishment, 420 Bloomfield Avenue, Caldwell, New Jersey 07006, 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 Caldwell Confectionery LLC'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.

¹ Two violations were documented on November 8, 2014, and two on April 6, 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.

§ 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, 28975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1)², no retailer may sell tobacco products 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 tobacco product purchasers are younger than 18 years of age.

Under 21 C.F.R. § 17.2, a \$5,501 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$5,501 against Respondent Caldwell Confectionery LLC. 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

² On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.