Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2016-H-1068)

Complainant

v.

HappyInLife, Inc. d/b/a McChord Mart,

Respondent.

Docket No. T-16-664

Decision No. TB742

Date: January 13, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, HappyInLife, Inc. d/b/a McChord Mart, located at 5105 Solberg Drive Southwest B, Lakewood, Washington 98499, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that McChord Mart 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 \$2,000 civil money penalty against Respondent McChord Mart. 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 \$2,000 civil money penalty, on Respondent HappyInLife, Inc. d/b/a McChord Mart, at 5105 Solberg Drive Southwest B, Lakewood, Washington 98499. Respondent filed an answer to CTP's complaint on June 18, 2016. I issued an Acknowledgement and Prehearing Order (APHO) on July 27, 2016, that set deadlines for parties' submissions, including the August 25, 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 August 25, 2016.

On October 4, 2016, 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). On the same date, CTP also filed a motion requesting that all pre-hearing exchange deadlines be extended for 30 days. In a letter issued by my direction, Respondent was given until October 20, 2016, to object to CTP's motion. Respondent did not file an objection to CTP's motion.

In a November 3, 2016 Order, I granted CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines. The Order allowed Respondent until November 16, 2016 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 November 28, 2016, indicating that Respondent did not comply with the Order Granting CTP's Motion to Compel. In a November 30, 2016 letter issued by my direction, Respondent was given until December 16, 2016, to object to CTP's motion. To date, Respondent has not filed an objection to CTP's Motion to Impose Sanctions.

II. Striking Respondent's Answer

On November 28, 2016, CTP filed a Motion to Impose Sanctions. In its November 28, 2016 Motion for Sanctions, CTP stated that "[s]anctions are appropriate for Respondent's failure to produce documents and comply with the Order [Granting CTP's Motion to Compel]...."

Due to noncompliance with my Acknowledgement and Pre-Hearing Order (APHO), my Order granting CTP's Motion to Compel, and my November 30, 2016 letter advising Respondent that failure to respond to motions and orders may result in 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:

- On February 24, 2015, CTP initiated a previous civil money penalty action, CRD Docket Number C-15-1369, FDA Docket Number FDA-2015-H-0541, against Respondent¹ for two² violations of 21 C.F.R. pt. 1140 within a twelve month period. CTP alleged those violations to have occurred at Respondent's business establishment, 5105 Solberg Drive Southwest B, Lakewood, Washington 98499, on May 14, 2014, and September 29, 2014;
- The previous action concluded when an Initial Decision and Default Judgment was entered by an administrative law judge, "finding that all of the violations alleged in the Complaint occurred";
- At approximately 2:21 p.m. on December 1, 2015, at Respondent's business establishment, 5105 Solberg Drive Southwest B, Lakewood, Washington 98499, an FDA-commissioned inspector documented Respondent's staff selling a package of Camel Crush Menthol 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

¹ In the previous action, Respondent was identified as HappyInLife, Inc. / In Cha Choe d/b/a McChord Mart.

 $^{^{2}}$ Two violations were documented on May 14, 2014, and one on September 29, 2014. 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.

older.

These facts establish Respondent McChord Mart'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. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), 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.

A \$2,000 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$2,000 against Respondent HappyInLife, Inc. d/b/a McChord Mart. 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/

Catherine Ravinski Administrative Law Judge