

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,
(FDA No. FDA-2017-H-2474)

Complainant

v.

Iman Crown, Inc.
d/b/a Ever Green,

Respondent.

Docket No. T-17-3695

Decision No. TB2422

Date: February 1, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) began this matter by serving an Administrative Complaint (Complaint) on Respondent, Iman Crown, Inc. d/b/a Ever Green, at 6819 Loch Raven Boulevard, Towson, Maryland 21286, and by filing a copy of the Complaint with the Food and Drug Administration (FDA) Division of Dockets Management. The Complaint alleges that Ever Green impermissibly sold cigarettes to minors, held open packages of cigarettes intended for the sale of individual cigarettes, 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 Ever Green previously admitted to five violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose an \$11,182 civil money penalty against Respondent Ever Green. During the administrative proceeding, Respondent failed to comply with judicial directions and failed to appear for a pre-hearing conference. Therefore, 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 an \$11,182 civil money penalty, on Respondent, Iman Crown, Inc. d/b/a Ever Green, at 6819 Loch Raven Boulevard, Towson, Maryland 21286. On May 24, 2017, Respondent filed an Answer to CTP's complaint. On June 2, 2017, I issued an Acknowledgment and Prehearing Order (APHO) that set deadlines for the parties' submissions, including the July 12, 2017 discovery deadline.¹

On August 17, 2017, CTP filed a Motion to Compel Discovery. In its motion, CTP stated that on July 12, 2017, CTP served a Request for Production of Documents on Respondent, but had not received a response to its request. On August 17, 2017, CTP also filed a Motion to Extend Deadlines. An August 21, 2017 letter issued by my direction allowed Respondent until September 5, 2017 to file a response to CTP's Motion to Compel Discovery. The letter also granted CTP's Motion to Extend Deadlines and extended the parties' pre-hearing exchange deadlines.

On September 11, 2017, I issued an Order that granted CTP's Motion to Compel Discovery. I noted that Respondent had not filed a response to CTP's Motion to Compel Discovery and ordered Respondent to comply with CTP's Request for Production of Documents by September 25, 2017.

On October 3, 2017, CTP filed Complainant's Status Report and Motion to Impose Sanctions, indicating that Respondent had not complied with my September 11, 2017 Order. On that same date, CTP filed a Motion to Extend Deadlines. An October 4, 2017 letter issued by my direction allowed Respondent until October 18, 2017 to file a response to CTP's Motion to Impose Sanctions. The letter also granted CTP's Motion to Extend Deadlines. On October 17, 2017, CTP filed Complainant's Status Report and Withdrawal of Motion to Impose Sanctions, indicating that Respondent provided a response to CTP's Request for Production of Documents. On November 21, 2017, CTP filed its pre-hearing exchange. Respondent did not file a pre-hearing exchange by the December 15, 2017 deadline.

On December 20, 2017, I issued an Order Scheduling Pre-Hearing Conference. The telephone pre-hearing conference was scheduled for January 5, 2018, at 11:30 AM Eastern Time. The parties were provided with a call in telephone number and passcode. However, Respondent did not appear at the pre-hearing conference call or otherwise provide any response to the Order that scheduled the pre-hearing conference.

¹ Along with its May 24, 2017 Answer, Respondent also filed a Waiver Request from using the DAB E-File System. I granted the Waiver Request in my June 2, 2017 APHO.

On January 8, 2018, I issued an Order giving Respondent until January 22, 2018, to show cause for its failure to appear at the pre-hearing conference. Respondent was informed that failure to respond to the Order 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.” As of the date of this Decision, a response to the Order has not been received.

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.

21 C.F.R. § 17.35(a).

Here, Respondent failed to appear at the January 5, 2018 pre-hearing conference call and did not comply with my January 8, 2018 Order. Respondent has failed to comply with orders and procedures governing this proceeding, and failed to defend the action. 21 C.F.R. § 17.35(a). Respondent’s misconduct has interfered with the speedy, orderly, or fair conduct of this proceeding. *Id.* Therefore, I find that sanctions are appropriate under 21 C.F.R. § 17.35.

The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure. 21 C.F.R. § 17.35(b). I find and conclude that Respondent’s misconduct is sufficiently egregious to warrant striking its May 24, 2017 Answer and issuing a decision without further proceeding. 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:

- On August 1, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-16-1297, FDA Docket Number FDA-2016-H-2036 (*see also* CRD Docket Number C-15-2280, FDA Docket Number FDA-2015-H-1446), against Respondent for five² violations of 21 C.F.R. pt. 1140 within a thirty-six month period. CTP alleged those violations to have occurred at Respondent's business establishment, 6819 Loch Raven Boulevard, Towson, Maryland 21286, on July 9, 2014, December 4, 2014, and January 12, 2016;
- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and agreed to pay a monetary penalty in settlement of the claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";
- On December 9, 2016, at Respondent's business establishment, 6819 Loch Raven Boulevard, Towson, Maryland 21286, an FDA-commissioned inspector observed a plastic jar containing individual cigarettes behind the sales counter. The most responsible person on duty stated that the establishment sells individual cigarettes.

These facts establish Respondent Ever Green'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),³ 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. Under 21 C.F.R. § 1140.14(a)(4), retailers are prohibited from breaking or otherwise opening any cigarette package to sell or distribute individual cigarettes.

² Two violations were documented on July 9, 2014 (sale to a minor and failure to verify the age of a purchaser), two on December 4, 2014 (sale to a minor and failure to verify the age of a purchaser), and two on January 12, 2016 (sale to a minor and failure to verify the age of a purchaser). 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.

³ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

Under 21 C.F.R. § 17.2, an \$11,182 civil money penalty is permissible for six violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$11,182 against Respondent Iman Crown, Inc. d/b/a Ever Green. 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