

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-1313)

Complainant,

v.

Mei Hong Du  
d/b/a Golden Restaurant,

Respondent.

Docket No. T-17-2638

Decision No. TB2011

Date: October 4, 2017

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Mei Hong Du d/b/a Golden Restaurant, that alleges that Golden Restaurant impermissibly sold cigarettes or smokeless 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 Golden Restaurant 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 Golden Restaurant. During the hearing process, Respondent has failed to comply with multiple judicial directions and orders. 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 Golden Restaurant. Respondent's timely filed answer to CTP's Complaint was received in the Civil Remedies Division on March 30, 2017. On April 10, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO) that explained to the parties what they must do to present evidence and arguments in this case. I explained that the parties may request copies of documents relevant to this case and that the requesting party must serve the request for documents no later than May 18, 2017. I further explained that a party receiving such a request must provide the requested documents no later than 30 days after the request has been made. As part of the discovery process, CTP served a Request for Production of Documents on Respondent on May 11, 2017.

On June 20, 2017, CTP filed a motion to compel discovery indicating that CTP had not received a response to its request for production of documents. *See* 21 C.F.R. § 17.23(a). On June 20, 2017, CTP also filed a motion to extend the deadlines. A June 21, 2017 letter issued by my direction allowed Respondent until July 6, 2017 to file a response to CTP's motion to compel discovery. On June 21, 2017, I also issued an Order that extended the parties' pre-hearing exchange deadlines.

On July 31, 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. In that Order, I stated that Respondent shall comply with CTP's request for production of documents by August 11, 2017. I further stated that "[f]ailure to do so may 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." The July 31, 2017 Order also extended the parties' pre-hearing exchange deadlines.

On August 14, 2017, CTP filed a Status Report and Motion to Impose Sanctions advising me that Respondent had not complied with my July 31, 2017 Order, and asking me to strike the Respondent's answer and issue a default judgment in this case. On August 14, 2017, CTP also filed a second motion to extend the pre-hearing exchange deadlines. In an August 18, 2017 letter issued by my direction, Respondent was given until September 1, 2017 to file a response to CTP's motion. The August 18, 2017 letter also extended the parties' pre-hearing exchange deadlines. To date, Respondent has not filed a response to CTP's Motion to Impose Sanctions.

## **II. Striking Respondent's Answer**

Pursuant to 21 C.F.R. § 17.35, I am granting CTP's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with multiple judicial

orders/directions. Specifically, Respondent has not complied with the deadline set forth in the Acknowledgment and Pre-Hearing Order for responding to any discovery request, the order granting CTP's motion to compel discovery issued on July 31, 2017, and finally the letter issued by my direction on August 18, 2017 soliciting a response to CTP's motion to impose sanctions. 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 here that Respondent's repeated failure to comply is 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 3, 2016, CTP initiated a previous civil money penalty action, FDA Docket Number FDA-2016-H-0239, against Respondent for three<sup>1</sup> violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 2136 Stenton Avenue, Philadelphia, Pennsylvania 19138, on December 2, 2014, and September 9, 2015. Complaint ¶ 10.
- The previous action was closed 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." Complaint ¶ 11.
- At approximately 1:50 PM on September 24, 2016, at Respondent's business establishment, 2136 Stenton Avenue, Philadelphia, Pennsylvania 19138, an FDA-commissioned inspector documented Respondent's staff selling a package of

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<sup>1</sup> Two violations were documented on December 2, 2014, and two on September 9, 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.

Maverick Menthol Box 100s 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. Complaint ¶ 8.

These facts establish Respondent Golden Restaurant'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)<sup>2</sup>, no retailer may sell cigarettes and/or smokeless tobacco 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 and/or smokeless tobacco 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 Mei Hong Du d/b/a Golden Restaurant. 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.

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/s/  
Catherine Ravinski  
Administrative Law Judge

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