

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2016-R-2885)

Complainant

v.

QM Enterprises, Inc.  
d/b/a BP,

Respondent.

Docket No. T-16-2070

Decision No. TB1329

Date: May 19, 2017

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, QM Enterprises, Inc. d/b/a BP, that alleges facts and legal authority sufficient to justify the imposition of a No-Tobacco-Sale Order against Respondent for a period of 30 calendar days. During the hearing process, Respondent has failed to comply with three separate judicial orders and directions. I therefore strike Respondent's answer and issue this decision of default judgment.

**I. Procedural History**

Respondent timely answered CTP's complaint opposing the No-Tobacco-Sale Order and requested a hearing. On November 8, 2016, I issued an Acknowledgment and Pre-Hearing Order 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 December 15, 2016. 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 December 15, 2016.

On January 26, 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 January 26, 2017, CTP also filed a motion to extend the deadlines. A January 30, 2017 letter issued by my direction allowed Respondent until February 13, 2017 to file a response to CTP's motion to compel discovery. On January 30, 2017, I also issued an Order that extended the parties' pre-hearing exchange deadlines.

On February 17, 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 March 3, 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 February 17, 2017 Order also extended the parties' pre-hearing exchange deadlines.

On March 24, 2017, CTP filed a motion to impose sanctions advising me that Respondent had not complied with my February 17, 2017 Order, and asking me to strike the Respondent's answer and issue a default judgment in this case. On April 10, 2017, Respondent filed a request for extension of time to file a response to CTP's motion to impose sanctions, stating that it was providing CTP with requested documents and continuing settlement negotiations. In an April 12, 2017 letter issued by my direction, Respondent was given until April 13, 2017 to file a response to CTP's motion. 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 three 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 February 17, 2017, and finally the letter issued by my direction on April 12, 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 that default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with my orders. 21 C.F.R. § 17.11. Specifically:

- On February 4, 2014, CTP initiated its first civil money penalty action, CRD Docket Number C-14-565, FDA Docket Number FDA-2014-H-0097, against Respondent for two<sup>1</sup> 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, 714 East Warren Avenue, Detroit, Michigan 48201, on February 24, 2013, and July 26, 2013;
- The first action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and agreed to pay a monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions;"
- On January 9, 2015, CTP initiated its second civil money penalty action, CRD Docket Number C-15-800, FDA Docket Number FDA-2014-H-2312, against Respondent for four 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, 714 East Warren Avenue, Detroit, Michigan 48201, on February 24, 2013, July 26, 2013, and December 17, 2014;
- The second action concluded when an Initial Decision and Default Judgment was entered by the administrative law judge, "finding that all of the violations alleged in the Complaint occurred;"
- At approximately 10:43 AM on November 28, 2015, at Respondent's business establishment, 714 East Warren Avenue, Detroit, Michigan 48201, an FDA-commissioned inspector documented Respondent's staff selling a package of

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<sup>1</sup> Two violations were documented on February 24, 2013, and one on July 26, 2013. 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.

Newport 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.

These facts establish that Respondent is liable 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. § 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). The regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1). The regulations also require retailers to verify, by means of photographic identification containing the purchaser's date of birth, that no tobacco product purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i).

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for five repeated violations of the regulations found at 21 C.F.R. pt. 1140. The maximum period of time for the first No-Tobacco-Sale Order received by a retailer is 30 calendar days. *See* Pub. L. 111-31, div. A, title I, § 103(q)(1)(A), June 22, 2009, 123 Stat. 1838, 1839; Food & Drug Admin., Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers at 5-6, *available at* <http://www.fda.gov/TobaccoProducts/Labeling/Rules/RegulationsGuidance/ucm447308.htm> (last updated Dec. 15, 2016).

## ORDER

For these reasons, I enter default judgment against Respondent QM Enterprises, Inc. d/b/a BP, in the form of a No-Tobacco-Sale Order, for a period of 30 calendar days. During this period of time, Respondent shall stop selling cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products regulated under the Federal Food, Drug, and Cosmetic Act. 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