Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1516)

Complainant,

v.

Kimberly R. Wart
d/b/a Midland Rails Liquor,

Respondent.

Docket No. C-15-23

Decision No. CR4301

Date: October 8, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated a $5,000 civil money penalty (CMP) action against Respondent for unlawfully selling cigarettes to minors and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, on three separate occasions, in violation of 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. During the hearing process, Respondent has failed to comply with three separate judicial directions, (1) to file its pre-hearing exchange, (2) to appear at a scheduled pre-hearing telephone conference, and (3) to show cause for failing to appear at the scheduled pre-hearing conference. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

Respondent timely answered CTP's complaint proposing the CMP and requested a hearing. I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines

for parties' submissions, including the December 22, 2014 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 December 22, 2014. On January 27, 2015, 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). CTP also moved to stay all deadlines citing Respondent's production of documents as necessary to complete its informal brief and supporting exhibits. On January 28, 2015, I extended all deadlines and provided Respondent until February 9, 2015, to reply to CTP's motion to compel discovery to show that it either did comply with CTP's December 22, 2014, Request for Production of Documents or to explain its failure to comply with the request.

On February 19, 2015, I issued an Order granting CTP's Motion to Compel Discovery because Respondent failed to file any response to CTP's Motion to Compel Discovery or to my January 28, 2015, Order. I stated that Respondent shall comply with CTP's Request for Production of Documents by March 23, 2015.

On March 3, 2015, I issued an Order further extending the deadlines in the January 28, 2015 Order for a period of 30 days. Then, the Order granting CTP's Motion to Compel Discovery was returned in the mail. Therefore, on April 6, 2015, I reissued two prior Orders, one granting CTP's Motion to Compel Discovery and the other extending the parties' exchange deadlines. I then learned of a second address for the Respondent, and as it had become evident that there were mail delivery issues, on May 12, 2015, I reissued the Order granting CTP's Motion to Compel and the Order extending the parties' exchange deadlines.

On June 16, 2015, CTP filed a Joint Motion to Extend Deadlines. Specifically, the Motion requested that the pre-hearing exchange deadlines in the May 12, 2015 Order be extended an additional 30 days. In a June 18, 2015, Order I extended the pre-hearing exchange deadlines as requested. Pursuant to that Order, CTP's pre-hearing exchange to Respondent was due July 27, 2015, and Respondent's pre-hearing exchange to CTP was due August 17, 2015.

On July 27, 2015, CTP filed its pre-hearing exchange. To date Respondent has not filed a pre-hearing exchange.

On September 8, 2015, I issued an Order Scheduling a Pre-Hearing Conference for September 21, 2015 at 1:00 pm Eastern Time. That Order provided a toll free telephone number for the parties to call to appear at the telephone pre-hearing conference. At the scheduled time, Deeona Gaskin, the attorney representing CTP, appeared at the pre-hearing conference. Respondent did not appear for the scheduled pre-hearing telephone

conference. At that time, Ms. Gaskin moved for a default judgment as Respondent had not appeared and had not submitted a pre-hearing exchange.

On September 22, 2015, I issued an Order informing Respondent that he had until October 2, 2015 to show cause for his failure to appear at the scheduled pre-hearing conference. In that Order I 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."

To date Respondent has not submitted any explanation for his failure to appear at the pre-hearing conference. On October 2, 2015, my office received an email from CTP stating, in pertinent part, that:

> Mr. Kimberly Wart (Respondent) recently called Deeona Gaskin and left a message. I called Mr. Wart today . . . . I explained to Mr. Wart that he had missed the Pre-Hearing Conference, and that he should contact you immediately for details on what to do next. Mr. Wart said he could not make long distance calls because there is a block on his phone. I told him I would inform you of his limitations, and pass on his request that your office call him . . . ."

II. Striking Respondent's Answer

Respondent failed to file its pre-hearing exchange, failed to appear at the scheduled pre-hearing conference and did not respond to my Order to show cause for his failure to appear. The record shows that Respondent did contact CTP, but he has not shown cause for his failure to appear at the scheduled pre-hearing conference. While Respondent informed CTP that he was unable to make long distance calls, the telephone number that was provided to appear at the pre-hearing conference was a toll free telephone number. Additionally, despite Respondent's statement that he could not make long distance calls, he was able to call and leave a message for Deeona Gaskin at CTP. Further, Respondent could have submitted a written explanation before the pre-hearing conference stating his concerns about his ability to appear. But, he did not. Additionally, he could have responded to my Order to show cause following the pre-hearing conference. But, again, he did not. There is no indication that Respondent has made any attempt to contact the Departmental Appeals Board.

I therefore strike Respondent's Answer, issue this default decision, and assume the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. §§ 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 egregious. *See* 21 C.F.R. § 17.35(b). Respondent failed to file its pre-hearing exchange. Further, there is no indication Respondent made any effort to appear at the scheduled

telephone pre-hearing conference, and has not responded to my Order to show cause for failing to appear at the pre-hearing conference. Respondent did not comply with my orders on three occasions nor did he provide any adequate justification for not doing so.

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:

- CTP previously issued a warning letter to Respondent Midland Rails Liquor on August 18, 2011, citing violations[1] of 21 C.F.R. pt. 1140 on July 18, 2011, at Respondent's business establishment, 10550 Ute Pass Avenue, Green Mountain Falls, Colorado 80819;

- On October 1, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-1333, FDA Docket Number FDA-2013-H-1138, against Respondent Midland Rails Liquor for three violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred on July 18, 2011, and March 27, 2013;

- The previous action concluded when Kim Wart, Respondent's authorized representative, settled the claims on Respondent's behalf. Mr. Wart signed an Acknowledgment Form, dated November 4, 2013, in which he "admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions."

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[1] In the complaint, CTP describes the action or actions that took place at Respondent Midland Rails Liquor's business establishment on July 18, 2011, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint dated September 18, 2013, and attached to the present complaint, however, CTP described two discrete violations at Respondent Midland Rails Liquor's business establishment on July 18, 2011: a violation of 21 C.F.R. § 1140.14(a), and a violation of 21 C.F.R. § 1140.14(b)(1). Therefore, I will infer that CTP's description in the present complaint of "a violation" occurring on July 18, 2011, was a typographical error.

The Administrative Law Judge closed the case on February 27, 2014;

- During a subsequent inspection of Respondent's business establishment, 10550 Ute Pass Avenue, Green Mountain Falls, Colorado 80819, on April 2, 2014, at approximately 2:16 p.m., FDA-commissioned inspectors documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age. The inspectors 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'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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes 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 purchasers are younger than 18 years of age.

I conclude, therefore, that a $5,000 civil money penalty is permissible under 21 C.F.R. § 17.2. This order becomes final and binding upon both parties after 30 days of the date of its issuance. 21 C.F.R. § 17.11(b).

/ s /
Catherine Ravinski
Administrative Law Judge