

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Vishwa Dev Rattan
d/b/a Low Bob's,

Respondent.

Docket No. C-15-825
FDA No. FDA-2015-H-0032

Decision No. CR4655

Date: July 5, 2016

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated a \$500 civil money penalty (CMP) action against Respondent for unlawfully selling tobacco products to minors, on two separate occasions, 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 two 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 failed to comply with two judicial directions. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

CTP served its complaint on Respondent on January 9, 2015. Initially, Respondent did not file an answer to CTP's complaint and I issued an Initial Decision and Default Judgment imposing a \$500 CMP. Following the issuance of my Initial Decision and Default Judgment, Respondent filed a motion to reopen the Initial Decision. I granted

Respondent's motion to reopen and Respondent later filed an answer. I then issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for parties' submissions, including the July 27, 2015 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 July 27, 2015. On September 3, 2015, 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 September 3, 2015, CTP also filed a motion to extend the deadlines. Pursuant to my direction, a September 8, 2015 letter allowed Respondent until September 21, 2015 to file a response to CTP's motion to compel discovery. On September 8, 2015, I also issued an Order that extended the parties' pre-hearing exchange deadlines.

On September 30, 2015, I issued an Order that granted CTP's motion to compel discovery. In that Order, I stated that Respondent shall comply with CTP's request for production of documents by October 20, 2015. The September 30, 2015 Order also further extended the parties' pre-hearing exchange deadlines.

On October 27, 2015, CTP filed an updated status report and a motion to impose sanctions advising me that Respondent had not complied with my September 30, 2015 Order and asking me to strike the Respondent's answer and issue a default judgment in this case.

On October 23, 2015, Respondent filed a motion asserting that he not be compelled to submit discovery because it was unduly burdensome. Pursuant to my direction, a November 3, 2015 letter allowed CTP until November 18, 2015 to file a response to Respondent's motion and assert why it needed the requested documents at issue. On November 3, 2015, I also issued an Order that extended the parties' pre-hearing exchange deadlines. On November 17, 2015, CTP filed its opposition to Respondent's request for a protective order. On December 3, 2015, I stayed the parties' pre-hearing exchange deadlines pending the resolution of this issue. On December 17, 2015, Respondent filed stipulations with the Court. On January 13, 2016, CTP filed an updated status report stating that "in light of statements made by Respondent in its Motion for Protective Order . . . and stipulations recently submitted by Respondent . . . CTP has now received sufficient documents and information from Respondent to proceed in this case."

On March 14, 2016, I issued an Order that set the pre-hearing exchange dates in this case. Both parties have filed timely pre-hearing exchanges. On April 11, 2016, I issued an Order Scheduling a Pre-Hearing Conference for May 11, 2016 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, Michael Shane, the attorney

representing CTP, appeared at the pre-hearing conference. Respondent did not appear for the scheduled pre-hearing telephone conference.

On May 12, 2016, I issued an Order informing Respondent that he had until May 23, 2016 to show cause for his failure to appear at the scheduled pre-hearing conference. In that Order I stated that: "Failure 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.

II. Striking Respondent's Answer

Respondent failed to appear at the scheduled pre-hearing conference and did not respond to my Order to show cause for his failure to appear. Respondent has not made any contact with this Court since December 17, 2015, the date Respondent filed its stipulations. Respondent's failure to effectively prosecute and defend actions taken over the course of the proceedings have interfered with the orderly and speedy processing of this case, further warranting imposition of sanctions. *See* 21 C.F.R. § 17.35(a) (1)(2) and (3).

Due to Respondent's failure to appear at the scheduled pre-hearing conference and failure to respond to my Order to show cause for his failure to appear, 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(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). Respondent did not comply with my orders on two 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:

- Respondent owns Low Bob's, an establishment that sells tobacco products and is located at 1907 North Greensburg Crossing, Greensburg, Indiana 47240. Complaint ¶ 3.
- During an inspection of Respondent's establishment on May 29, 2013, at approximately 6:20 PM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco . . . [.]". The inspector also observed that "the minor's identification was not verified before the sale" Complaint ¶ 10.
- On June 20, 2013, CTP issued a Warning Letter to Respondent regarding the inspector's observations from May 29, 2013. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- Initially, CTP did not receive a response to the Warning Letter, and on August 6, 2013 CTP sent Respondent a letter stating that it had not received a response to the Warning Letter. Vishwa Dev Rattan contacted CTP via telephone on November 27, 2013, and "stated that the employee who sold the tobacco product to the minor had been disciplined and all employees had been trained to sell tobacco products pursuant to federal law. Mr. Rattan also stated that the establishment's management would organize periodic surprise checks." Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment on June 27, 2014, at approximately 11:35 AM, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]". The inspectors also documented that "the minor's identification was not verified before the sale" Complaint ¶ 1.

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 distributed or offered for sale in any state 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). The regulations prohibit the sale of cigarettes and smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo

identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent violated the prohibition against selling tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on May 29, 2013, and June 27, 2014. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$500, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge