

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

C C Patel LLC  
d/b/a Carousel Deli and Pizzeria,

Respondent.

Docket No. C-15-3647  
FDA No. FDA-2015-H-2841

Decision No. CR4519

Date: February 4, 2016

**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 tobacco to minors, on three 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 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 failed to comply with a judicial direction regarding CTP's discovery request. I therefore strike Respondent's answer and issue this decision of default judgment.

**I. Procedural History**

Respondent timely answered CTP's complaint. Administrative Law Judge Margaret G. Brakebusch issued an Acknowledgement and Prehearing Order (APHO)<sup>1</sup> that set deadlines for parties' submissions, including the October 28, 2015 deadline to request

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<sup>1</sup> The case was transferred from Judge Brakebusch to me on January 28, 2016.

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 October 28, 2015. On December 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 December 3, 2015, CTP also filed a motion to extend the deadlines. Pursuant to Judge Brakebusch's direction, a December 7, 2015 letter allowed Respondent until December 22, 2015 to file a response to CTP's motion to compel discovery. On December 8, 2015, Judge Brakebusch issued an Order that extended the parties' pre-hearing exchange deadlines.

On January 4, 2016, Judge Brakebusch issued an Order that granted CTP's motion to compel discovery. Judge Brakebusch noted that Respondent had not filed a response to CTP's motion to compel discovery. In that Order, Judge Brakebusch stated that Respondent shall comply with CTP's request for production of documents by January 26, 2016. She further 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. Within five (5) days of Respondent's deadline to comply with discovery, CTP must file a status report notifying me whether Respondent has complied with discovery.

The January 4, 2016 Order also further extended the parties' pre-hearing exchange deadlines.

On January 28, 2016, CTP filed an updated status report advising that Respondent had not complied with the January 4, 2016 Order. On January 28, 2016, CTP also filed a motion to impose sanctions that asked the Administrative Law Judge to strike the Respondent's answer and issue a default judgment in this case.

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

Respondent failed to file a response to CTP's motion to compel discovery, and to comply with the January 4, 2016 Order compelling discovery responses to be provided by January 26, 2016. Respondent did not comply with CTP's discovery requests. Respondent has not made any contact with this Court since September 24, 2015, the date Respondent timely filed its answer and notice of appearance. 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 the imposition of sanctions. *See* 21 C.F.R. § 17.35(a) (1)(2) and (3).

Due to Respondent's noncompliance with the January 4, 2016 Order, 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 failed to comply with the January 4, 2016 Order, nor did it 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 the orders. 21 C.F.R. § 17.11. Specifically:

- Respondent owns Carousel Deli and Pizzeria, an establishment that sells tobacco products and is located at 28 John Ringo Road, Ringoes, New Jersey 08551. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-15-1052, FDA Docket Number FDA-2015-H-0224, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period.<sup>2</sup> Specifically, those violations included two violations on April 5, 2014, when Respondent sold tobacco to a minor and failed to verify, by means of photographic identification, that the tobacco purchaser was 18 years of age or older;<sup>3</sup> and two violations on August 12, 2014, when Respondent sold cigarettes to a minor, and failed to verify, by means of photographic identification, that the tobacco purchaser was 18 years of age or older. Complaint ¶ 10; January 23, 2015 Complaint ¶ 10.

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<sup>2</sup> In this prior complaint, Respondent's name was "C C Patel LLC / Manish Amin d/b/a Carousel Deli and Pizzeria."

<sup>3</sup> CTP counted the two violations on April 5, 2014, as one violation.

- The previous civil money penalty action concluded when Vinus Patel, Respondent's authorized representative, settled the action with CTP on Respondent's behalf. Ms. Patel signed an Acknowledgment Form, dated March 2, 2015 in which she "admitt[ed] that the violations . . . occurred, waiv[ed] her ability to contest the violations in the future, and stat[ed] that she understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on March 12, 2015. Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment conducted on April 29, 2015, at approximately 6:12 PM, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Red Man smokeless tobacco . . . ." 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 or 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 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 April 5, 2014, August 12, 2014, and April 29, 2015. 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 \$5,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$5,000 is warranted and so order one imposed.

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/s/  
Steven T. Kessel  
Administrative Law Judge