

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1968)

Complainant

v.

P and C Deli LLC / Prite Patel
d/b/a P and C Deli,

Respondent.

Docket No. C-15-438

Decision No. CR3755

Date: April 2, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, P and C Deli LLC/Prite Patel d/b/a P and C Deli, at 1500 Church Street, Philadelphia, Pennsylvania 19124, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that P and C Deli impermissibly sold cigarettes to minors, 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. CTP seeks to impose a \$250 civil money penalty against Respondent P and C Deli. During the hearing process, Respondent has failed to comply with two separate judicial directions to Respondent to a CTP request for discovery. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

Respondent timely answered CTP's complaint denying the allegations and requesting a hearing. I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for parties' submissions, including the January 22, 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 January 22, 2015. On March 3, 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 filed a motion on March 3, 2015, requesting that all deadlines be held in abeyance.

On March 4, 2015, I issued an Order extending the briefing deadlines for 45 days and ordering Respondent to provide the requested documents by March 16, 2015, or provide an explanation for its failure to comply with the discovery deadlines. Respondent has failed to provide a response.

II. Pending Motions

On March 19, 2015, CTP filed a motion for sanctions. Specifically, CTP has requested that Respondent's Answer be stricken and that an Initial Decision and Default Order be entered against Respondent imposing the \$250 civil money penalty.

Respondent has failed to comply with the APHO and the March 4, 2015, Order compelling discovery responses to be provided by March 16, 2015. Further, Respondent has not filed a response to the motion for sanctions.

I therefore grant CTP's motion for sanctions by 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 egregious. *See* 21 C.F.R. § 17.35(b). Respondent did not comply with the Orders on two occasions, nor did it provide any adequate justification for not doing so. The record contains no evidence that suggests the Respondent lacks the capacity to respond. Instead, it appears that Respondent has chosen to ignore its discovery obligations and further ignore any requests for information.

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:

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on November 25, 2014, CTP served the Complaint on Respondent P and C Deli by United Parcel Service.

- At approximately 5:29 p.m. on August 19, 2013, at Respondent's business establishment, 1500 Church Street, Philadelphia, Pennsylvania 19124, an FDA-commissioned inspector observed Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age.
- In a warning letter dated October 10, 2013, CTP informed Respondent of the inspector's August 19, 2013 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 1:54 p.m. on May 24, 2014, at Respondent's business establishment, 1500 Church Street, Philadelphia, Pennsylvania 19124, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box 100's cigarettes to a person younger than 18 years of age.

These facts establish Respondent P and C Deli'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.

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

