

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

JLYC LLC
d/b/a SeaTac Deli Market,

Respondent.

Docket No. C-13-998
FDA Docket No. FDA-2013-H-0826

Decision No. CR3133

Date: February 27, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, JLYC LLC d/b/a SeaTac Deli Market, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$500.

CTP initiated this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent unlawfully sold cigarettes to a minor, failed to verify that a cigarette purchaser was of sufficient age and utilized a self-service display of regulated tobacco products in a non-exempt facility, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$500.

On July 12, 2013, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that within 30 days Respondent should pay the penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty.

Respondent timely answered the Complaint and requested a hearing. On August 23, 2013, I issued an Acknowledgment and Prehearing Order (Pre-hearing Order) that set deadlines for the parties' submissions and scheduled a mandatory settlement conference to be held on September 25, 2013, at 3:00 PM ET. On September 25, 2013, the parties participated in the settlement conference but were unable to reach a settlement agreement during the conference. On October 2, 2013, by my direction, the staff attorney assisting me in this matter sent a letter to the parties that reminded the parties that they must comply with the deadlines and provisions set out in the Pre-hearing Order. On November 6, 2013, my staff attorney sent another letter to the parties that restated the deadlines for the parties' submissions and contained the informal briefs that I issued on that same date.

On December 6, 2013, CTP's counsel filed a motion to compel discovery, pursuant to 21 C.F.R. § 17.23, along with a copy of Complainant's request for the production of documents (Request). In her motion, counsel stated that CTP served the Request on Respondent on November 1, 2013, and that Respondent had until December 2, 2013, to comply with the Request. *See* 21 C.F.R. § 17.23(a). On December 11, 2013, by my direction, my staff attorney sent a letter to the parties that gave Respondent until January 3, 2014, to file its reply to CTP's motion to compel discovery or comply with the Request. Respondent neither complied with the Request by the deadline nor filed a reply to CTP's motion to compel discovery.

On January 23, 2014, I directed my staff attorney to send another letter to inform the parties that any party may move for sanctions when the opposing party fails to comply with a procedure governing the proceeding; engages in misconduct that interferes with the speedy, orderly, or fair conduct of the hearing; or fails to comply with a discovery provision. 21 C.F.R. § 17.35 (a) and (c). On February 3, 2014, CTP's counsel moved for sanctions against Respondent for its failure to either file a reply to CTP's motion to compel discovery or comply with the Request.

On February 5, 2014, Respondent e-mailed my staff attorney a letter addressed to me. After ensuring that Complainant received a copy via email, the staff attorney forwarded the letter to me. In the letter, Respondent objected to the charges made against it and made some arguments that might address the merits of the case, but it did not explain why it failed to comply with the Request. On February 6, 2014, I issued an Order to the parties that gave Respondent until February 14, 2014, to comply with the Request or I would impose sanctions against Respondent and enter a default judgment against it. To date, Respondent has neither complied with the Request nor explained why it has failed to do so. Therefore, pursuant to 21 C.F.R. § 17.35(c)(3), I sanction Respondent by striking its Answer.

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 Order. 21 C.F.R. § 17.11(a). Specifically, CTP's Complaint alleges that:

- Respondent owns SeaTac Deli Market, an establishment that sells tobacco products and is located at 18050 Des Moines Memorial Drive, Sea Tac, Washington 98148. Complaint ¶ 3.
- On May 22, 2012, during an inspection of Respondent's establishment, an FDA-commissioned inspector observed that Respondent "u[tilized] a self-service display in a non-exempt facility" Complaint ¶ 10.
- On September 13, 2012, CTP issued a Warning Letter to SeaTac Deli Market explaining that the inspector's May 22, 2012 observation constituted a violation of a regulation found at 21 C.F.R. § 1140.16(c). In addition to describing the violation, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if it failed to correct the violation. The letter also stated that it was Respondent's responsibility to comply with the law. Complaint ¶ 10.
- On December 20, 2012, Sukki Kim, Respondent's management, responded in writing to the Warning Letter on Respondent's behalf. "Mr. Kim stated that the tobacco products were relocated so that all transactions would now be face-to-face." Complaint ¶ 11.

