Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-1921)

Complainant

v.

Fernandez Mini Market Corp. / Jorge Fernandez d/b/a Fernandez Mini Market,

Respondent.

Docket No. C-15-390

Decision No. CR3779

Date: April 14, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Fernandez Mini Market Corp. / Jorge Fernandez, d/b/a Fernandez Mini Market, at 344 Orange Street, Springfield, Massachusetts 01108, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Fernandez Mini Market impermissibly sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, 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 \$500 civil money penalty against Respondent Fernandez Mini Market. During the hearing process, Respondent has failed to comply with judicial directions to respond to CTP's 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 and requested a hearing. I issued an Acknowledgement and Prehearing Order (APHO) on December 24, 2014 that set deadlines for parties' submissions, including the January 23, 2015 deadline to request that the opposing party provide copies of documents relevant to this case. The APHO further stated that a party receiving such a request must provide the requested documents no later than 30 days after the request. Also, item #16 "Sanctions for failure to comply with orders," stated that these included but were not limited to the dismissal of the complaint or answer if a party failed to comply with any order.

CTP served Respondent with its request for documents on January 22, 2015. On February 27, 2015, CTP filed a motion to compel discovery indicating that Respondent did not respond to its request within the time limit, together with proof of delivery. *See* 21 C.F.R. § 17.23(a). CTP also moved to stay all deadlines, citing Respondent's production of documents as necessary to prepare its pre-hearing exchange.

On March 19, 2015, by letter, I suspended CTP's pre-hearing exchange deadline. In addition, I ordered Respondent to file its reply to CTP's motion to compel discovery or file a protective order within 10 days from receipt of the letter dated March 19, 2015. Furthermore, Respondent was again given notice that the ALJ may impose sanctions on a party for failure to comply with a discovery order pursuant to 21 CFR 17.35. The name and contact information for the Attorney handling the case was provided, and Respondent was invited to call if there were any questions, or any information was required. To date, Respondent has neither filed a motion for a protective order, nor complied with CTP's discovery request.

II. Striking Respondent's Answer

The record does not contain any evidence that Respondent complied with any discovery requests, despite being ordered by the Court to do so on March 19, 2015.

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 sufficiently egregious to warrant striking the answer and issuing a decision. See 21 C.F.R. § 17.35(b). Respondent first ignored a discovery request that was documented as having been received, after having been put on notice the previous month that doing so could result in an effective dismissal of the case. In March 2015, given another opportunity to respond to the discovery request and again warned of the consequences of inaction, Respondent did not comply with my order, provided no justification for not doing so, and in fact never responded at all, although urged to do so

and given contact information at the DAB. 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. Respondent has made no effort to respond to CTP's motion to compel discovery or to comply with the discovery request, by either producing documents or filing a protective order before the extended deadline.

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:

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on November 20, 2014, CTP served the Complaint on Respondent Fernandez Mini Market by United Parcel Service.

- At approximately 12:54 PM on July 23, 2013, at Respondent's business establishment, 344 Orange Street, Springfield, Massachusetts 01108, an FDA-commissioned inspectors observed Respondent's staff selling a package of Newport Non-Menthol Box 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;
- In a warning letter dated September 5, 2013, CTP informed Respondent of the inspector's July 23, 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 10:07 AM on May 21, 2014, at Respondent's business establishment, 344 Orange Street, Springfield, Massachusetts 01108, FDA-commissioned inspectors documented Respondent's staff selling a package of Marlboro 100's 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 Fernandez Mini Market'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 or smokeless tobacco 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 cigarette purchasers are younger than 18 years of age.

I conclude, therefore, that a \$500 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).

Catherine Ravinski
Administrative Law Judge