

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-2674)

Complainant

v.

Floridan Foods, “LLC”
d/b/a The Green Store Food Mart 107,

Respondent.

Docket No. C-15-3487

Decision No. CR4507

Date: January 15, 2016

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated a \$250 civil money penalty (CMP) action against Respondent for unlawfully selling cigarettes to minors, 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 has 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 opposing the CMP and requested a hearing. On August 28, 2015, I issued an Acknowledgment and Pre-Hearing Order that explained to the parties what they must do to present evidence and arguments in this case. I explained that the parties may request copies of documents relevant to this case and that the requesting party must serve the request for documents no later than September 28, 2015. I further explained that a party receiving such a request must provide the requested

documents no later than 30 days after the request has been made. As part of the discovery process, CTP served a Request for Production of Documents on Respondent on September 28, 2015.

On November 6, 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 November 6, 2015, CTP also filed a motion to extend the deadlines. Pursuant to my direction, a November 9, 2015 letter allowed Respondent until November 25, 2015 to file a response to CTP's motion to compel discovery. On November 9, 2015, I also issued an Order that extended the parties' pre-hearing exchange deadlines.

On December 2, 2015, I issued an Order that granted CTP's motion to compel discovery. I noted that Respondent had not filed a response to CTP's motion to compel discovery. In that Order, I stated that Respondent shall comply with CTP's request for production of documents by December 21, 2015. I 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 December 2, 2015 Order also further extended the parties' pre-hearing exchange deadlines.

On December 24, 2015, CTP filed an updated status report advising me that Respondent had not complied with my December 2, 2015 Order. On December 24, 2015, CTP also filed a motion to impose sanctions that asked me to strike the Respondent's answer and issue a default judgment in this case. The time for Respondent to respond to CTP's motion to impose sanctions has passed, and Respondent did not file a response.

II. Striking Respondent's Answer

Respondent failed to file a response to CTP's motion to compel discovery, failed to comply with the December 2, 2015 Order compelling discovery responses to be provided by December 21, 2015, and failed to file a response to CTP's motion to impose sanctions. Respondent did not comply with any of CTP's discovery requests. Respondent has not made any contact with this Court since August 21, 2015, the date Respondent timely filed its answer. 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 noncompliance with the December 2, 2015 Order compelling discovery, 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 December 2, 2015 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 my orders. 21 C.F.R. § 17.11. Specifically:

- At approximately 3:14 p.m. on December 15, 2014, at Respondent's business establishment, 11339 Tamiami Trail East, Naples, Florida 34113, an FDA-commissioned inspector observed Respondent's staff selling a package of Marlboro Gold Pack cigarettes to a person younger than 18 years of age;
- In a warning letter dated January 22, 2015, CTP informed Respondent of the inspector's December 15, 2014 observation, and that such action violates federal law, 21 C.F.R. § 1140.14(a). The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action;
- At approximately 9:07 p.m. on April 2, 2015, at Respondent's business establishment, 11339 Tamiami Trail East, Naples, Florida 34113, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age.

These facts establish Respondent The Green Store Food Mart 107'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.

Order

For these reasons, I enter default judgment in the amount of \$250 against Respondent Floridan Foods, “LLC” d/b/a The Green Store Food Mart 107. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/ s /
Margaret G. Brakebusch
Administrative Law Judge