

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2016-H-1355)

Complainant

v.

Fred Ford and Betty Ford  
d/b/a F. and B. Gro.,

Respondent.

Docket No. T-16-719

Decision No. TB648

Date: December 22, 2016

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Fred Ford and Betty Ford d/b/a F. and B. Gro., located at 22062 Augusta Highway, Cottageville, South Carolina 29435, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that F. and B. Gro. 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 F. and B. Gro. During the hearing process, Respondent has failed to comply with two separate judicial directions regarding CTP's discovery request. I therefore strike Respondent's answer and issue this decision of default judgment.

## **I. Procedural History**

CTP began this matter by serving an administrative complaint, seeking a \$250 civil money penalty, on Respondent Fred Ford and Betty Ford d/b/a F. and B. Gro., at 22062 Augusta Highway, Cottageville, South Carolina 29435. Respondent filed an answer to CTP's complaint on June 30, 2016. I issued an Acknowledgement and Prehearing Order (APHO) on July 21, 2016, that set deadlines for parties' submissions, including the August 19, 2016 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 August 18, 2016.

On September 27, 2016, 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). On the same date, CTP also filed a motion requesting that all pre-hearing exchange deadlines be extended for 30 days. In a letter issued by my direction, Respondent was given until October 12, 2016, to object to CTP's motion. Respondent did not file an objection to CTP's motion.

In an October 27, 2016 Order, I granted CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines. The Order allowed Respondent until November 10, 2016 to comply with CTP's discovery request. In granting CTP's Motion to Compel Discovery, I explained that failure to comply with CTP's discovery request could 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. CTP subsequently filed a Motion to Impose Sanctions on November 21, 2016, indicating that Respondent did not comply with the Order Granting CTP's Motion to Compel. On the same date, CTP also filed a Motion to Extend Deadlines, requesting that all pre-hearing exchange deadlines be extended for 30 days. In a November 21, 2016 letter issued by my direction, Respondent was given until December 6, 2016, to object to CTP's motion. To date, Respondent has not filed an objection to CTP's Motion to Impose Sanctions.

## **II. Pending Motions**

On November 21, 2016, CTP filed a Motion to Impose Sanctions. In its November 21, 2016 Motion for Sanctions, CTP stated that "Respondent has neither produced any of the requested documents, nor contacted Complainant or Counsel for Complainant regarding this matter."

Due to noncompliance with my Acknowledgement and Pre-Hearing Order (APHO) and my Order granting CTP's Motion to Compel, 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(a)(1), 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).

### **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:

- At approximately 10:14 a.m. on May 20, 2015, at Respondent's business establishment, 22062 Augusta Highway, Cottageville, South Carolina 29435, an FDA-commissioned inspector observed Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age;
- In a warning letter dated June 25, 2015, CTP informed Respondent of the inspector's May 20, 2015 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 4:40 p.m. on November 5, 2015, at Respondent's business establishment, 22062 Augusta Highway, Cottageville, South Carolina 29435, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age.

These facts establish Respondent F. and B. Gro.'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.

