

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

E-Z Food Mart Inc.,

Respondent.

Docket No. C-15-2451
FDA No. FDA-2015-H-1631

Decision No. CR4464

Date: November 25, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated a \$5,000 civil money penalty (CMP) action against Respondent for unlawfully selling tobacco products to minors, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, on three 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 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. I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for parties' submissions, including the July 27, 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 July 23, 2015. On September 1, 2015, CTP filed a motion to compel discovery indicating that Respondent did not respond to its request for production of documents. *See* 21 C.F.R. § 17.23(a). On September 1, 2015, CTP also filed a motion to extend the deadlines. Pursuant to my direction, a September 3, 2015 letter allowed Respondent until September 17, 2015 to file an objection to CTP's motion to compel discovery. That letter also extended the parties' pre-hearing exchange deadlines.

On September 18, 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 October 2, 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. CTP shall file a status report by October 7, 2015, informing me whether or not Respondent has provided the documents requested and whether it is seeking sanctions against Respondent.

Emphasis removed.

On October 7, 2015, CTP filed an updated status report advising me that Respondent had not complied with my September 18, 2015 Order. On October 7, 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. In an October 14, 2015 Order, I stayed all existing deadlines in this case until I issued a ruling on CTP's motion to impose sanctions.

II. Striking Respondent's Answer

Respondent failed to file a response to CTP's motion to compel discovery, and to comply with the September 18, 2015 Order compelling discovery responses to be provided by October 2, 2015. Respondent did not comply with CTP's discovery requests. Respondent has not made any contact with this Court since June 18, 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 September 18, 2015 Order, 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 September 18, 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:

- Respondent owns E-Z Food Mart Inc., an establishment that sells tobacco products and is located at 951 East Market Street, Jeffersonville, Indiana 47130. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-14-1649, FDA Docket Number FDA-2014-H-1143, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period.¹ Specifically, those violations included two violations on May 5, 2013, when Respondent sold tobacco products to a minor and failed to verify, by means of photographic identification, that the tobacco purchaser was 18 years of age or older;² and two violations on February 12, 2014, when Respondent sold tobacco products to a minor, and failed to verify, by means of photographic identification, that the tobacco purchaser was 18 years of age or older. Complaint ¶ 10; August 6, 2014 Complaint ¶ 10.
- The previous civil money penalty action concluded when Traci McCain, Respondent's authorized representative, settled the action with CTP on Respondent's behalf. Ms. McCain signed an Acknowledgment Form, dated

¹ In this prior complaint, Respondent's name was "E Z Food Mart, Inc. / Traci McCain d/b/a E Z Food Mart."

² CTP counted the two violations on May 5, 2013, as one violation.

October 20, 2014, in which she “admitt[ed] that the violations . . . occurred, waiv[ed] her ability to contest the violations in the future, and stat[ed] that she understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions.” The Administrative Law Judge closed the case on October 30, 2014. Complaint ¶ 11.

- During a subsequent inspection of Respondent’s establishment conducted on January 6, 2015, at approximately 4:50 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco . . . [.]” Complaint ¶ 1. The inspectors also documented that “the minor’s identification was not verified before the sale . . . [.]” Complaint ¶ 1.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 906(d) of the Act. 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). The regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent violated the prohibition against selling tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on May 5, 2013, February 12, 2014, and January 6, 2015. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$5,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$5,000 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge