

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Zenex International Group, LLC
d/b/a Zenex Gas N Go / Sunoco Food Mart,

Respondent.

Docket No. C-15-3482
FDA No. FDA-2015-H-2669

Decision No. CR4534

Date: February 22, 2016

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated a \$500 civil money penalty (CMP) action against Respondent for unlawfully selling tobacco to minors, on two separate occasions, 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 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 discovery, 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. On September 1, 2015, Administrative Law Judge Margaret G. Brakebusch issued an Acknowledgement and Prehearing Order (APHO)¹ that set deadlines for parties' submissions, including the October 2, 2015

¹ The case was transferred from Judge Brakebusch to me on January 29, 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 September 28, 2015. On November 5, 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 5, 2015, CTP also filed a motion to extend the deadlines. Pursuant to a November 9, 2015 letter issued at Judge Brakebusch's direction, Respondent had until November 23, 2015 to file an objection to CTP's motion to compel discovery and the pre-hearing exchange deadlines were extended for the parties. On November 10, 2015, pursuant to Judge Brakebusch's direction, another letter was issued that corrected Respondent's pre-hearing exchange deadline because it was set forth incorrectly in the November 9, 2015 letter.

On November 30, 2015, Judge Brakebusch issued an Order that granted CTP's motion to compel discovery. Judge Brakebusch noted that Respondent did not file an objection to CTP's motion to compel discovery. In that Order, Judge Brakebusch stated that Respondent shall comply with CTP's request for production of documents by December 15, 2015. She 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 December 21, 2015 informing me of whether it is seeking sanctions.

Emphasis removed. The November 30, 2015 Order also further extended the parties' pre-hearing exchange deadlines.

On December 18, 2015, CTP filed an updated status report advising that Respondent had not complied with the November 30, 2015 Order. On December 18, 2015, CTP also filed a motion to impose sanctions that asked the Administrative Law Judge to strike the Respondent's answer and issue a default judgment in this case. A December 21, 2015 letter, issued at Judge Brakebusch's direction, gave Respondent until January 5, 2016 to file an objection to CTP's motion to impose sanctions. To date Respondent has not filed an objection to CTP's motion.

II. Striking Respondent's Answer

Respondent failed to file a response to CTP's motion to compel discovery, and to comply

with the November 30, 2015 Order compelling discovery responses to be provided by December 15, 2015. Respondent did not comply with 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 the imposition of sanctions. *See* 21 C.F.R. § 17.35(a) (1)(2) and (3).

Due to Respondent's noncompliance with the November 30, 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 November 30, 2015 Order and did not 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 the orders. 21 C.F.R. § 17.11. Specifically:

- Respondent owns Zenex Gas N Go / Sunoco Food Mart, an establishment that sells tobacco products and is located at 5450 Palm Beach Boulevard, Fort Myers, Florida 33905. Complaint ¶ 3.
- During an inspection of Respondent's establishment on December 23, 2014, at approximately 3:43 PM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Camel Crush Menthol cigarettes . . . [.]" The inspector also observed that "the minor's identification was not verified before the sale" Complaint ¶ 10.
- On January 29, 2015, CTP issued a Warning Letter to Respondent regarding the inspector's observations from December 23, 2014. The letter explained that the

observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.

- On February 10, 2015, FDA received an undated letter from the Respondent, in response to the Warning Letter stating that the “Respondent spoke with and retrained ‘the cashier in question’ on the establishment’s tobacco sales policy” and that “Respondent requires all of its employees to verify the identification of anyone who attempts to purchase tobacco products.” CTP responded with a February 24, 2015 letter acknowledging receipt of the establishment’s response and reminding Respondent of its continuing obligation to be in compliance with the Act and its implementing regulations. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment conducted on April 1, 2015, at approximately 2:29 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes” 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 cigarettes or smokeless tobacco 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 December 23, 2014 and April 1, 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 \$500 which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

Steven T. Kessel
Administrative Law Judge