

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-0079)

Complainant

v.

Naqvis Foods Inc. / Zafar Naqvi
d/b/a 7-Eleven 34193,

Respondent.

Docket No. C-15-880

Decision No. CR4118

Date: August 13, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Naqvis Foods Inc. / Zafar Naqvi d/b/a 7-Eleven 34193 located at 8455 Colesville Road, Silver Spring, Maryland 20910, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that 7-Eleven 34193 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 \$2,000 civil money penalty against Respondent 7-Eleven 34193. 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

On January 13, 2015, CTP served an administrative complaint seeking a \$2,000 civil money penalty on Respondent 7-Eleven 34193, at 8455 Colesville Road, Silver Spring, Maryland 20910. Respondent filed an answer to CTP's complaint on March 12, 2015. I issued an Acknowledgement and Prehearing Order (APHO) on April 09, 2015, that set deadlines for parties' submissions, including the May 14, 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 May 13, 2015.

On June 19, 2015, 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. On July 09, 2015, I issued an order granting CTP's Motion to Compel Discovery, giving Respondent the final deadline of July 22, 2015 to comply with CTP's discovery request. CTP subsequently filed a Motion to Impose Sanctions on July 23, 2015, and an Updated Status Report on July 23, 2015, indicating that Respondent did not comply with the Order Granting Motion to Compel.

II. Pending Motions

In its July 23, 2015 Updated Status Report, CTP stated that “[t]o date, Respondent has neither complied with CTP's Motion to Compel Discovery nor filed a Motion for Protective Order.” Due to this noncompliance, 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).

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:

- CTP previously issued a warning letter to Respondent 7-Eleven 34193 on October 18, 2012, citing violations of 21 C.F.R pt. 1140 on August 06, 2012, at Respondent's business establishment, 8455 Colesville Road, Silver Spring, Maryland 20910;
- On August 16, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-1111, FDA Docket Number FDA 2013-H-0917, against Respondent for two violations of 21 C.F.R pt. 1140 within a twelve-month period. CTP alleged those violations to have occurred on August 06, 2012 and January 16, 2013;
- The previous action concluded when Zafar Naqvi, Respondent's authorized representative, settled the claims on Respondent's behalf. On September 06, 2013, Mr. Naqvi signed an Acknowledgement Form in which he "admitt[ed] that the violations...occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he 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 2, 2013;
- On April 15, 2014, CTP initiated a previous civil money penalty action, CRD Docket Number C-14-940, FDA Docket Number 2014-H-0443, against Respondent for three violations of 21 C.F.R Part 1140 within a twenty-four month period. CTP alleged those violations to have occurred on October 21, 2013;
- The previous action concluded when Zafar Naqvi, Respondent's authorized representative, settled the claims on Respondent's behalf. On June 03, 2014, Mr. Naqvi signed an Acknowledgement Form in which he "admitt[ed] that the violations...occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he 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 June 12, 2014;
- At approximately 11:31 A.M. on July 9, 2014, at Respondent's business establishment, 8455 Colesville Road, Silver Spring, Maryland 20910. FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age.

These facts establish Respondent 7-Eleven 34193'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(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.

A \$2,000 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$2,000 against Respondent Naqvis Foods Inc. / Zafar Naqvi d/b/a 7-Eleven 34193. 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/
Catherine Ravinski
Administrative Law Judge