

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,
(FDA No. FDA-2018-H-0798)

Complainant

v.

OM Shiv Groceries Inc.
d/b/a Bodie's Dairy Markets,

Respondent.

Docket No. T-18-1383

Decision No. TB3174

Date: October 16, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, OM Shiv Groceries Inc. d/b/a Bodie's Dairy Markets, at 33306 Main Street, Dagsboro, Delaware 19939, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Bodie's Dairy Markets impermissibly sold smokeless tobacco to minors and failed to verify, by means of photo identification containing a date of birth, that a purchaser was 18 years of age or older, 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 \$559 civil money penalty against Respondent Bodie's Dairy Markets. During the hearing process, Respondent failed to comply with four judicial directions regarding CTP's discovery request. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Background

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on February 23, 2018, CTP served the complaint on Respondent Bodie's Dairy Markets by United Parcel Service. Respondent timely filed an answer denying the allegations.

On March 15, 2018, I issued an Acknowledgment and Pre-hearing Order (APHO) acknowledging receipt of Respondent's answer and setting forth case procedures and deadlines. The APHO contained a provision that set out instructions regarding a party's request for production of documents. That provision states, in part, that a party had until April 16, 2018, to request that the other party provide copies of documents relevant to this case. The order also stated that, pursuant to 21 C.F.R. § 17.23(a), a party receiving such a request must provide the requested documents no later than 30 days after the request has been made.

On May 23, 2018, CTP filed a Motion to Compel Discovery stating that it served its Request for Production of Documents (RFP) on Respondent on April 16, 2018. CTP stated that it did not receive a response from Respondent regarding its RFP, and requested that I issue an order requiring Respondent to comply. On June 14, 2018, I granted CTP's Motion to Compel Discovery and ordered Respondent to comply with CTP's RFP by July 5, 2018.

On July 3, 2018, Respondent filed a response to CTP's RFP. However, on July 18, 2018, CTP filed a Motion to Compel Further Responses stating that Respondent's response to CTP's RFP was "incomplete and does not properly respond to Complainant's requested documents for production." CTP's Motion to Compel Further Responses requested I order Respondent to comply with CTP's RFP in its entirety. On August 13, 2018, I granted CTP's Motion to Compel Further Responses and ordered Respondent to comply with CTP's RFP by August 29, 2018. I warned Respondent that failure to comply 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.

On September 21, 2018, CTP filed a Motion to Impose Sanctions stating that Respondent has not produced any additional documents as ordered. CTP requested I strike Respondent's answer, and issue an initial decision and default judgment imposing a civil money penalty against Respondent. In a September 21, 2018 letter issued by my direction, Respondent was given until October 5, 2018 to file a response to CTP's Motion to Impose Sanctions. To date, Respondent has not responded to the Motion to Impose Sanctions or to the September 21, 2018 letter.

Therefore, pursuant to 21 C.F.R. § 17.35, I am granting CTP's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with four separate judicial directions. Specifically, Respondent failed to comply with my March 15, 2018 APHO, Respondent failed to comply with my June 14, 2018 order, and Respondent failed to comply with my August 13, 2018 order requiring it to comply with CTP's RFP. Additionally, Respondent failed to respond to CTP's Motion to Impose Sanctions or the September 21, 2018 letter. This repeated conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default.

II. Default Decision

Striking Respondent's answer leaves the complaint unanswered. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- At approximately 4:38 p.m. on May 31, 2017, at Respondent's business establishment, 33306 Main Street, Dagsboro, Delaware 19939, an FDA-commissioned inspector documented Respondent's staff selling a package of Skoal Pouches Classic Mint smokeless tobacco to a person younger than 18 years of age;
- In a warning letter dated June 22, 2017, CTP informed Respondent of the inspector's May 31, 2017 documented violation, and that such action violates federal law. 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 8:36 p.m. on February 2, 2018, at Respondent's business establishment, 33306 Main Street, Dagsboro, Delaware 19939, an FDA-commissioned inspector documented Respondent's staff selling a package of Skoal Long Cut Classic Mint smokeless tobacco to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

These facts establish Respondent Bodie's Dairy Markets' 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); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1), no retailer may sell smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no smokeless tobacco purchasers are younger than 18 years of age.

A \$559 civil money penalty is permissible under 21 C.F.R. § 17.2.

