Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2015-H-0109)

Complainant

v.

C K Food and Fuel MN Inc. d/b/a C K Food and Fuel,

Respondent.

Docket No. C-15-910

Decision No. CR4037

Date: July 13, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, C K Food and Fuel MN Inc. d/b/a C K Food and Fuel, at 4751 Nicollet Avenue, Minneapolis, Minnesota 55419, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that C K Food and Fuel impermissibly sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 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. The complaint likewise alleges that Respondent C K Food and Fuel had previously admitted to three violations of C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,000 civil money penalty against Respondent C K Food and Fuel.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 15, 2015, CTP served the complaint on Respondent C K Food and Fuel by United Parcel Service. In the complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time in which to file an answer.

CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

I. Procedural History

On March 13, 2015, Respondent C K Food and Fuel filed an answer to the complaint. On March 20, 2015, I issued an Acknowledgment and Pre-Hearing Order which established discovery request and production deadlines.

On April 27, 2015, CTP served Respondent with a request for production of documents. As established in the Acknowledgment and Pre-Hearing Order, Respondent was given 30 days to provide the requested documents, which Respondent has failed to do.

On June 1, 2015, CTP filed a Motion to Compel Discovery and Motion to Extend Deadlines. On June 2, 2015, I granted CTP's motions and ordered Respondent to comply with CTP's request for production of documents or file a motion for protective order by July 1, 2015. Respondent was warned that failure to comply with the order may result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations in the complaint. CTP filed a status report on July 6, 2015, indicating that Respondent has not produced any documents as requested by CTP and has failed to comply with any court orders or discovery requests. Due to this noncompliance, I am striking Respondent's answer. 21 C.F.R. § 17.35 (c)(3).

II. 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 C K Food and Fuel on September 5, 2013, citing violations¹ of 21 C.F.R. pt. 1140 on July 23, 2013, at

¹ In the complaint, CTP describes the action or actions that took place at Respondent C K Food and Fuel's business establishment on July 23, 2013, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint dated May 8, 2014, and attached to the present complaint, however, CTP described two discrete

Respondent's business establishment, 4751 Nicollet Avenue, Minneapolis, Minnesota 55419;

- On May 13, 2014, CTP initiated a previous civil money penalty action, CRD Docket Number C-14-1095, FDA Docket Number FDA-2014-H-0608, against Respondent C K Food and Fuel for three violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred on July 23, 2013 and January 9, 2014;
- The previous action concluded when Martin Onuh, Respondent's authorized representative, settled the claims on Respondent's behalf. On June 14, 2014, Mr. Onuh signed an Acknowledgment 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 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 27, 2014;
- At approximately 1:16 p.m. on July 14, 2014, at Respondent's business establishment, 4751 Nicollet Avenue, Minneapolis, Minnesota 55419, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age. The inspectors 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 C K Food and Fuel'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. § 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 a tobacco product to any person younger than 18 years of age. Further, under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

A \$5,000 civil money penalty is permissible under 21 C.F.R. § 17.2.

violations at Respondent C K Food and Fuel's business establishment on July 23, 2013: a violation of 21 C.F.R. § 1140.14(a) and a violation of 21 C.F.R. § 1140.14(b)(1). Therefore, I will infer that CTP's description in the present complaint of "a violation" occurring on July 23, 2013, was a typographical error.

Order

For these reasons, I enter default judgment in the amount of \$5,000 against Respondent C K Food and Fuel MN Inc. d/b/a C K Food and Fuel. 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