Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-1563)

Complainant

v.

Kenrick Harris d/b/a North Coit Quick Stop,

Respondent.

Docket No. C-15-71

Decision No. CR3879

Date: May 20, 2015

RULING GRANTING MOTION FOR SUMMARY DECISION

The Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) has moved for summary decision against Respondent, Kenrick Harris d/b/a North Coit Quick Stop. In its motion, CTP argues that a civil money penalty of \$500 should be imposed against Respondent, based on undisputed material facts. Specifically, CTP alleges that North Coit Quick Stop 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.

I. Procedural History

CTP began this matter by serving an administrative complaint on Respondent, North Coit Quick Stop, at 502 North Coit Street, Florence, South Carolina 29501, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely answered CTP's complaint admitting the allegations but contesting the amount of the civil money penalty. I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges. Additionally, the APHO stated that either party could file a Motion for Summary Judgment and that the opposing party may respond no later than 30 days after the motion was filed.

CTP filed its pre-hearing exchange on April 14, 2015. Respondent's pre-hearing exchange was due on or before May 5, 2015. As of the date of this order, Respondent has not filed its pre-hearing exchange.

On April 14, 2015, CTP filed a Motion for Summary Judgment. Respondent's response to the Motion was due on or before May 14, 2015. As of the date of this order, Respondent has not filed a response.

II. Analysis and Ruling

A. Failure to Provide Pre-hearing Exchange

The regulations at 21 C.F.R. § 17.35(a)(1)-(2), quoted below, state that a failure to file an exchange or explain the failure to file an exchange may result in sanctions.

The presiding officer may sanction a person, including any party or counsel for:

(1) [f]ailing to comply with an order, subpoena, rule or procedure governing the proceeding;

(2) [f]ailing to prosecute or defend an action[.] ... If a party fails to prosecute or defend an action under this part after service of a [pre-hearing order], the presiding officer may dismiss the action or may issue an initial decision imposing penalties and assessments.

Respondent's failure to file an exchange timely is a basis for me to impose sanctions against it. Among those sanctions, I may impose the civil money penalty sought by CTP. As a result, the civil money penalty as sought by CTP could be entered against Respondent for its failure to comply with the APHO.

B. Motion for Summary Judgment

On April 14, 2015, CTP filed a Motion for Summary Judgment. CTP makes the following allegations to support its motion:

- At approximately 5:09 p.m. on October 31, 2013, at Respondent's business establishment, 502 North Coit Street, Florence, South Carolina 29501, an FDA-commissioned inspector observed Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age. The inspector also observed 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. CTP Ex. 3 at 1-2.
- In a warning letter dated January 9, 2014, CTP informed Respondent of the inspector's October 31, 2013 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action. CTP Ex. 8 at 1-2.
- At approximately 11:13 a.m. on April 9, 2014, at Respondent's business establishment, 502 North Coit Street, Florence, South Carolina 29501, 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. CTP Ex. 3 at 2-3.

CTP asserts that these allegations as supported by documentary evidence are sufficient to establish a basis for issuing a summary decision against Respondent. CTP further contends that, based on the undisputed facts, a civil money penalty of \$500 should be imposed.

Summary decision is appropriate in a case "if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law. 21 C.F.R. § 17.17(b). Additionally, in examining the evidence for purposes of deciding whether summary decision is appropriate, I must draw all inferences in the light that is most favorable to the party that opposes the motion. *U.S. v. Diebold, Inc.*, 369 U.S. 654, 655 (1962). Here, the inferences that I draw from the evidence CTP has submitted remain undisputed as Respondent has provided nothing to the contrary. In its defense, Respondent has

only provided an answer which admits the violations as alleged. This is not enough to overcome a Motion for Summary Judgment supported by affidavits and other documentary evidence. As a result, I find that there are no genuine issues of material fact.

Therefore, I find that these facts establish Respondent North Coit Quick Stop'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(a), no retailer may sell cigarettes to any person younger than 18 years of age. 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 \$500 civil money penalty is permissible under 21 C.F.R. § 17.2.

III. Order

For these reasons, CTP's Motion for Summary Judgment is GRANTED and I enter judgment in the amount of \$500 against Respondent Kenrick Harris d/b/a North Coit Quick Stop.

/s/

Catherine Ravinski Administrative Law Judge