

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-2096)

Complainant

v.

Gary Best Stockyards Inc. / Gary Best
d/b/a Koo-Koos Nest,

Respondent.

Docket No. C-15-577

Decision No. CR3918

Date: June 1, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Gary Best Stockyards Inc. / Gary Best d/b/a Koo-Koos Nest, at 3045 East Sangamon Avenue, Springfield, Illinois 62702, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Koo-Koos Nest impermissibly used a vending machine in a non-exempt facility, sold cigarettes to minors, and failed to verify that cigarette 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. CTP seeks to impose a \$2,000 civil money penalty against Respondent Koo-Koos Nest. Respondent has failed to comply with judicial directions to comply with discovery requests. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

The Respondent timely filed an answer to CTP's complaint on January 5, 2015. I issued an Acknowledgement and Prehearing Order (APHO) on January 23, 2015, that set deadlines for parties' submissions, including the February 23, 2015 deadline to request that the opposing party provide copies of documents relevant to this case. The APHO further stated that a party receiving such a request must provide the requested documents no later than 30 days after the request. Also, item #16 "Sanctions for failure to comply with orders," stated that these included but were not limited to the dismissal of the complaint or answer if a party failed to comply with any order.

CTP served Respondent with its request for documents on February 18, 2015. On March 25, 2015, CTP filed a Motion to Compel Discovery, requesting " that an order be entered to require Respondent to comply with the Request for Production of Documents in its entirety." CTP also moved to hold deadlines in abeyance, citing the need for "sufficient time to review the requested documents."

On April 8, 2015, I advised both parties that Respondent had until April 15, 2015 to either reply to CTP's Motion to Compel Discovery, or produce the requested documents. I further advised that failure to comply with discovery requests could result in sanctions.

On April 24, 2015, I ordered Respondent to comply with CTP's Request for Production of Documents by May 1, 2015. I also reiterated that noncompliance 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. The Respondent failed to comply with the discovery requests, and CTP subsequently moved to impose sanctions.

On May 7, 2015, I advised both parties that Respondent had until May 15, 2015 to reply to CTP's Motion to Impose Sanctions, and failure to comply could result in sanctions. To date, Respondent has failed to comply with discovery requests.

II. Striking Respondent's Answer

Respondent has neither complied with discovery requests, nor provided any explanation for noncompliance, despite being ordered to do so. On April 8, 2015, I directed Respondent to either reply to CTP's Motion to Compel Discovery, or produce the requested documents. Then on April 24, 2015, I ordered Respondent to comply with discovery requests. Even more, on May 7, 2015, I advised Respondent to reply to CTP's Motion to Impose Sanctions for noncompliance of discovery requests. Along with these three judicial directions, I informed Respondent that noncompliance could result in an effective dismissal of this case.

The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or noncompliance, and I find Respondent's failure to comply with discovery requests sufficient to warrant striking the answer and issuing a decision. 21 C.F.R. § 17.35. I hereby strike Respondent's answer, and assume the facts alleged in CTP's complaint to be true. See 21 C.F.R. §§ 17.35(c) (3), 17.11(a).

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. 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. 21 C.F.R. § 17.11. Specifically:

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on December 9, 2014, CTP served the complaint on Respondent Koo-Koos Nest by United Parcel Service.

- Respondent owns Koo-Koos Nest, an establishment that sells tobacco products and is located at 3045 East Sangamon Avenue, Springfield, Illinois 62702. Complaint ¶ 3.
- During an inspection of Respondent's establishment on January 13, 2014, an FDA-commissioned inspector observed a violation for using a vending machine in a non-exempt facility. "Specifically, during the inspection, the owner told the inspector that minors are allowed to enter the facility with an adult before 9:00 PM." Complaint ¶ 10.
- On March 6, 2014, CTP issued a Warning Letter to Respondent regarding the inspector's observation from January 13, 2014. The letter explained that the observation constituted a violation of the regulation found at 21 C.F.R. § 1140.14(c), and that the named violation was 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 violation, 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.
- Gary Best responded to the Warning Letter on May 7, 2014, by phone. "Mr. Best indicated that he no longer allows minors to enter the premises at any time, even when accompanied by a parent. Mr. Best also stated that he would add signage to

the establishment to indicate that it is now an adult-only facility that does not allow minors to enter.” Complaint ¶ 11.

- During a subsequent inspection of Respondent’s establishment on June 13, 2014, at approximately 4:58 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Marlboro Menthol cigarettes from a vending machine in Respondent’s establishment . . . [.]” 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 provide that a retailer may sell cigarettes or smokeless tobacco only in direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine), 21 C.F.R. § 1140.14(c), except where no person younger than 18 years of age is present in or allowed to enter the establishment at any time, 21 C.F.R. § 1140.16(c)(2)(ii). The regulations prohibit the sale of cigarettes 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 cigarette 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 using a vending machine in a non-exempt facility, 21 C.F.R. § 1140.14(c), on January 13, 2014, and June 13, 2014. Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on June 13, 2014. On that same date, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette 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 \$2,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$2,000 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge