

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

AARCH, Inc.
d/b/a Cool Valley BP,

Respondent.

Docket No. C-13-904
FDA Docket No. FDA-2013-H-0732

Decision No. CR2924

Date: September 17, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against AARCH, Inc. d/b/a Cool Valley BP (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$2,000 civil money penalty. Although Respondent timely filed an answer and request for hearing in response to the Complaint, it subsequently failed to comply with my pre-hearing order scheduling a mandatory settlement conference. I issued a show cause order directing Respondent to explain why it failed to comply with my pre-hearing order. The show cause order informed Respondent that failing to respond or to demonstrate good cause for its non-compliance would result in sanctions. Respondent did not file a response. Therefore, I sanction Respondent by striking its answer, entering a default judgment against Respondent, and ordering that Respondent pay a civil money penalty in the amount of \$2,000.

CTP initiated this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent unlawfully sold a tobacco product to a minor on three separate occasions and twice failed to verify that a purchaser of a tobacco product was of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301 – 399d, and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$2,000 for these violations.

On July 12, 2013, I issued an Acknowledgement and Pre-hearing Order (Pre-hearing Order) in this case to notify the parties of a “**mandatory settlement conference**” scheduled for August 14, 2013, at 1:00 PM ET.

Pre-hearing Order ¶ 3. Respondent failed to comply with the Pre-hearing Order and appear at the mandatory settlement conference as instructed. In further violation of the Pre-hearing Order, Respondent failed to provide the telephone number where it could be reached at the time scheduled for the settlement conference.

Notwithstanding Respondent's failure to comply with the Pre-hearing Order, the staff attorney assisting me with this case attempted to contact Respondent on three separate occasions. On August 14, 2013, the staff attorney attempted to contact Respondent's representative twice at the number Respondent provided in its answer. On the staff attorney's first attempt, there was neither an answer nor a voicemail box to leave a message. On the staff attorney's second attempt, a male who identified himself as “an employee” of AARCH, Inc., answered the call and provided the purported cell phone number of Respondent's representative. The staff attorney called the number provided and left a message for Respondent's representative. On August 16, 2013, the staff attorney again called the cell phone number and left another message for Respondent's representative.

As stated in the Pre-hearing Order, Respondent was required to provide the telephone number where it can be reached at least five (5) days prior to the settlement conference. Pre-Hearing Order ¶ 2. I assume Respondent received the Pre-hearing Order five days after the date it was placed in the mail. *See* 21 C.F.R. § 17.30(c). Pursuant to the Pre-hearing Order, Respondent should have filed its contact information by August 9, 2013. As of August 20, 2013, Respondent had not provided its contact information or returned the messages left by the CRD staff attorney.

To determine whether Respondent had good cause for failing to comply with the Pre-hearing Order, on August 20, 2013, I issued an Order to Show Cause (Order). I ordered Respondent to explain why it failed to provide the telephone number where it could be reached at the time scheduled for the settlement conference and why it failed to appear at the mandatory settlement conference. Order at 2. The Order explained that I might accept Respondent's late response if it could show that it had good cause for the delay. *Id.* The Order further explained if Respondent could not show good cause, I might dismiss its request for hearing and enter a default judgment. *Id.*; *See* 21 C.F.R. § 17.35(a)(1)-(3)(e).

Moreover, the Order informed Respondent that if I did not receive its response in writing by September 4, 2013, I would assume that it had nothing to submit, and I would impose sanctions against Respondent for failing to comply with the Order. Order at 2. As of September 16, 2013, I have not received a response from Respondent.

Respondent had the obligation to maintain contact with my office, to participate in the mandatory settlement conference that I scheduled, or to explain why it did not do so. Respondent's complete failure to communicate with me following its filing of an answer in this case -- despite repeated efforts by my office to contact it -- constitutes failure to comply with my pre-hearing orders, failure to defend this cause of action, and misconduct that interferes with the speedy, orderly, or fair conduct of the hearing in this case. 21 C.F.R. § 17.35(a)(1)-(3). Therefore, as authorized by the regulations, I strike Respondent's answer and enter a default judgment pursuant to the provisions of 21 C.F.R. § 17.35.

Striking Respondent's answer leaves the Complaint in this case unanswered. 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 and Respondent's abandonment of this proceeding. 21 C.F.R. § 17.11(a). In support of that conclusion, I make the following findings of fact and conclusions of law:

On June 21, 2013, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. Specifically, CTP's Complaint alleges that:

- Respondent owns Cool Valley BP, an establishment that sells tobacco products and is located at 1790 South Florissant Road, Saint Louis, Missouri 63121. Complaint ¶ 3.

- On August 24, 2011, an FDA-commissioned inspector observed two violations of 21 C.F.R. Part 1140 at Cool Valley BP. Specifically, the inspector observed a “Sale of cigarettes or smokeless tobacco to a person younger than 18 years of age . . .” and observed that Respondent failed “to verify[,] by means of photo identification, containing the bearer’s date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age” Complaint ¶ 12.
- “[O]n November 17, 2011, CTP issued a Warning Letter to Harsimran LLC, d/b/a Cool Valley BP.” The letter informed Respondent of the violations the FDA-commissioned inspector observed at the establishment on August 24, 2011, and explained that Respondent’s failure to correct the violations “may result in a civil money penalty action, or other regulatory action by [the] FDA.” CTP further explained that the Warning Letter was not intended to provide an exhaustive list of violations and that Respondent was responsible for complying with the law. Complaint ¶ 12.
- “[The] FDA did not receive a response to the Warning Letter. UPS records show that the Warning Letter was received on November 18, 2011, by [‘Ariane’]. CTP’s research shows that, at the time the Warning Letter was issued, KSD Petroleum LLC owned Cool Valley BP. CTP also contacted . . . the registered agent for KSD Petroleum LLC, by telephone on May 23, 2012. [The registered agent] confirmed ownership of both Harsimran LLC and KSD Petroleum LLC, that KSD Petroleum owns Cool Valley BP, and that he received the November 2011 Warning Letter addressed to Harsimran LLC for the violations at Cool Valley BP.” Complaint ¶ 13.
- “On June 11, 2012, CTP initiated a civil money penalty action against KSD Petroleum LLC for another violation of 21 C.F.R. § 1140.14(a).”¹ Specifically, “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on February 8, 2012, at approximately 7:05 PM CST.” Complaint ¶ 11.
- On August 16, 2012, the civil money penalty action “concluded with a default judgment entered against Respondent” that ordered Respondent “to pay a civil money penalty in the amount of \$250.” Complaint ¶ 11.
- On October 18, 2012, FDA-commissioned inspectors documented two additional violations of 21 C.F.R. Part 1140 at Respondent’s establishment.

¹ CTP does not allege that Harsimran LLC and AARCH, Inc. are the same legal entity owned by KSD Petroleum LLC. However, I will infer that they are.

The inspectors documented a violation of 21 C.F.R. § 1140.14(a) when “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 8:20 PM[.]” The inspectors also documented a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor’s identification was not verified before the sale” Complaint ¶ 1.

- On October 24, 2012, CTP issued a Notice of Compliance Check Inspection (Notice) informing Respondent that an inspection had been conducted on October 18, 2012, “and that during the inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 8:20 PM.” The Notice also warned Respondent “that other potential violations of [the] federal tobacco law may have been observed,” and if “CTP determined that there were additional violations of federal law, the establishment may receive further notification from [the] FDA.” Complaint ¶ 2.

I find that these facts, which I must assume are true, 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 sold or distributed in violation of regulations issued under section 906(d) of the Act, codified at 21 U.S.C. § 387f(d). *See* 21 U.S.C. § 387(a)(7)(B); 21 C.F.R. § 1140.1(b). The regulations prohibit the sale of cigarettes or smokeless tobacco 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 purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

In the present case, Respondent committed five violations of 21 C.F.R. Part 1140 within a 24-month period. First, on August 24, 2011, Respondent unlawfully sold a regulated tobacco product to a minor and failed to verify, by means of photo identification, that the purchaser was 18 years of age or older. 21 C.F.R. § 1140.14(a)-(b)(1). Subsequently, on February 8, 2012, Respondent again unlawfully sold a regulated tobacco product to a minor. 21 C.F.R. § 1140.14(a). On October 18, 2012, Respondent yet again sold a regulated tobacco product to a minor and failed to verify, by means of photo identification, that the purchaser was 18 years of age or older. 21 C.F.R. § 1140.14(a)-(b)(1). Respondent’s actions and omissions at the same retail outlet constitute violations of law for which a civil money penalty is merited.

