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

Center for Tobacco Products, (FDA No. FDA-2015-H-5090)

Complainant

v.

Baba Jawala Singh II, Inc. d/b/a 7-Eleven Store 26065A,

Respondent.

Docket No. T-16-1677

Decision No. TB874

Date: February 23, 2017

ORDER GRANTING COMPLAINANT'S MOTION TO IMPOSE SANCTIONS AND INITIAL DECISION AND DEFAULT JUDGMENT

As explained below, I grant Complainant's Motion to Impose Sanctions, strike Respondent's answer, and issue this decision of default judgment against the Respondent, Baba Jawala Singh II, Inc. d/b/a 7-Eleven Store 26065A.

I. Procedural History

CTP began this matter by serving an administrative complaint, seeking a \$500 civil money penalty, on Respondent Baba Jawala Singh II, Inc. d/b/a 7-Eleven Store 26065A, at 4208 59th Street West, Bradenton, Florida 34209. Respondent filed an answer to CTP's complaint on February 18, 2016.

On July 22, 2016, CTP filed a Motion to Compel Discovery indicating that Respondent did not respond to its Request for Production of Documents. On the same date, CTP also filed a motion requesting that all deadlines be extended for 30 days. On August 3, 2016, Judge Booker issued an order that granted CTP's motion to extend deadlines and changed the previously scheduled hearing date to October 18, 2016. On September 9, 2016, this

case was transferred to me. On September 30, 2016, I issued an Order Scheduling a Telephone Conference, to discuss the status of the case and to resolve any outstanding issues, which took place October 21, 2016.

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During the telephone conference, CTP indicated that Respondent had not responded to its Request for Production of Documents. At that time, Respondent acknowledged that it had received the Request for Production of Documents but had not responded. On October 25, 2016, I granted CTP's Motion to Compel and gave Respondent until November 7, 2016 to comply with CTP's request. In that order, I reminded Respondent that failure to comply with CTP's discovery request could result in Sanctions, including the issuance of an Initial Decision and Default Judgment, resulting in Respondent's liability for the violations listed in the complaint, including a civil money penalty.

CTP subsequently filed a Motion to Impose Sanctions on November 14, 2016, indicating that Respondent did not comply with my order granting CTP's Motion to Compel. In a November 16, 2016 letter issued by my direction, Respondent was given until December 1, 2016, to object or otherwise respond to CTP's motion.

On November 30, 2016, Respondent filed a response stating that "I can only backtrack [sic] my sales data 90 day [sic], so hence I will not be able to print out data." Respondent requested CTP provide proof of purchase for the tobacco sale in question to "research further." On January 9, 2017, CTP filed an Updated Status Report requesting that I grant its Motion to Impose Sanctions.

II. Striking Respondent's Answer

In its November 14, 2016 Motion to Impose Sanctions, CTP stated that "[s]anctions are appropriate for Respondent's failure to produce documents and comply with the Order, and an appropriate sanction is to strike Respondent's Answer and enter a Default Judgment against Respondent." Respondent's November 30, 2016 response to CTP's Motion did not object to it in any fashion, but stated only that it was unable to review sales data over 90 days old and therefore could not provide any data.

Respondent has failed to produce documents in response to CTP's Requests for Production and otherwise comply with my Order requiring it to participate in the exchange process. Sanction is therefore appropriate pursuant to 21 C.F.R. § 17.35(a). The issue is whether CTP's proposed sanction – striking Respondent's Answer and

¹ CTP's Motion to Impose Sanctions recounts additional communications between the parties on November 4, 2016, wherein Respondent's principal contacted CTP counsel via e-mail and stated she could not review transactions older than 90 days, and requesting proof of purchase and other identifying information from CTP, some of which was already available in the Complaint.

issuing default judgment – is the appropriate one. The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and be sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

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After careful consideration, I have concluded that this penalty is indeed appropriate. Respondent's explanation for failing to produce any documents in response to CTP's Requests for Production – its inability to access sales data older than 90 days – applies only to documentation related to the actual sale of tobacco products that took place on March 19, 2015, and October 2, 2015 (Request #4). However, CTP made several other requests to which Respondent apparently could have responded, including: training materials (Request #5); documentation of policies and procedures related to tobacco sales (Request #6); documentation of employee discipline; disciplinary policies related to tobacco sales (Request #7); and federal and state tax returns (Request #8). All these requests relate to materials that should be readily available to a business owner.

Thus, even if I accept Respondent's proffered explanation for not being able to produce documents related to sales data, Respondent has made no effort to produce any other documentation requested by CTP, explain why it could not produce it, or object to any aspect of CTP's requests, despite being ordered to do so on several occasions, and warned of the consequences of failing to comply. Given that CTP filed its Motion to Compel on July 22, 2016, Respondent has had more than sufficient time to comply with at least some of CTP's discovery requests, but has not done so.

Due to noncompliance with my October 25, 2016 Order granting CTP's Motion to Compel, I am striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. §§ 17.35(a)(1), 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(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

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² I note despite presently claiming to be unable to access data more than 90 days old, Respondent asserted in its Feb. 18, 2016 Answer that it had reviewed its electronic journal of sales on October 2, 2015, and confirmed no sales of Grizzly long cut smokeless tobacco. Answer at 1. The period of time between the alleged tobacco sale in question and Respondent's Answer is well over 90 days.

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 order. 21 C.F.R. § 17.11. Specifically:

- Respondent owns 7-Eleven Store 26065A, an establishment that sells tobacco products and is located at 4208 59th Street West, Bradenton, Florida 34209. Complaint ¶ 7-8.
- During an inspection of Respondent's establishment on March 19, 2015, at an unspecified time, an FDA-commissioned inspector documented that a person younger than 18 years of age was able to purchase a tobacco product. The inspector also documented the "failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth." Complaint ¶ 10.
- On April 30, 2015, CTP issued a Warning Letter to Respondent regarding the inspector's observations from March 19, 2015. The Warning Letter stated that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur. Complaint ¶ 10.
- During a subsequent inspection of Respondent's establishment on October 2, 2015, at approximately 11:37 AM, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco . . . [.]" The inspector also documented that "the minor's identification was not verified before the sale " Complaint ¶ 9.

These facts establish Respondent 7-Eleven Store 26065A'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 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); 81 Fed Reg. 28,974, 28975-76 (May 10, 2016). The regulations prohibit the sale of tobacco products 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 tobacco product 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 selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on

March 19, 2015, and October 2, 2015. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product 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.

ORDER

For these reasons, I grant Complainant's Motion to Impose Sanctions, strike Respondent's answer, and enter default judgment in the amount of \$500 against Respondent Baba Jawala Singh II, Inc. d/b/a 7-Eleven Store 26065A. 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

Bill Thomas
Administrative Law Judge