

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

Center for Tobacco Products,
(FDA No. FDA-2016-H-2167)

Complainant

v.

Bruce Tobacco for Less LLC
d/b/a Bruce Discount Tobacco / Tobacco for Less,

Respondent.

Docket No. T-16-1415

Decision No. TB2425

Date: February 5, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Bruce Tobacco for Less LLC d/b/a Bruce Discount Tobacco / Tobacco for Less, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$550. For the reasons outlined below, I enter judgment against Respondent and assess a civil money penalty of \$550.

I. Procedural History.

On September 2, 2016, CTP served its Complaint on Respondent by United Parcel Service (UPS), pursuant to 21 C.F.R. §§ 17.5 and 17.7. It asserted that Respondent impermissibly sold cigarettes to minors and failed to verify that cigarette purchasers were 18 years of age or older, in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and its implementing regulations found at 21 C.F.R. pt. 1140.

CTP seeks a civil money penalty of \$550. In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should pay the proposed penalty, file an answer, or request an extension within which to file an answer. After initially requesting an extension of time to do so, Respondent through counsel timely filed its Answer, Mitigating Circumstances and Affirmative Defenses of Respondent (Answer) on November 2, 2016.

On November 10, 2016, I issued an Acknowledgment and Pre-Hearing Order which established a schedule to regulate the course of discovery and the parties' submission of evidence and arguments. On November 14, 2016, counsel for Respondent filed a Notice of Withdrawal as Respondent's Counsel.

On January 26, 2017, CTP filed a Motion to Compel Discovery, asserting Respondent had not responded to its timely served document production request. On the same date, CTP also requested an extension of the pre-hearing exchange deadlines. Through a by-direction letter, I gave Respondent additional time, until February 14, 2017, to file a response to CTP Motion to Compel Discovery. I also issued an order extending the parties' pre-hearing exchange deadlines.

On February 13, 2017, the U.S. Postal Service returned these documents, which had been sent to Respondent's address of record on January 31, 2017. At my direction, on February 22, 2017, these documents were re-issued to Respondent at an alternate address. I again extended Respondent's deadline to file its response to CTP's Motion to Compel Discovery to March 3, 2017.

Respondent failed to file a response to CTP's Motion to Compel Discovery. On March 13, 2017, I issued an Order granting CTP's Motion to Compel Discovery, and directing Respondent to comply with CTP's Request for Production of Documents by March 28, 2017.

On March 30, 2017, CTP filed an Updated Status Report and Motion to Impose Sanctions. CTP stated that Respondent failed to comply with the Request for Production of Documents. It therefore requested that Respondent's Answer be stricken from the record and that a default judgment in favor of CTP be issued.

I provided Respondent additional time, until April 28, 2017, to respond to CTP's Motion to Impose Sanctions. I again extended the parties' pre-hearing exchange deadlines, and advised them that no further extensions would be granted. On April 28, 2017, Respondent submitted its response to CTP's Motion to Impose Sanctions via e-mail. Respondent indicated it could not produce the documents requested by CTP "because I don't have the records. They are almost three years old and I didn't keep them."

In light of this response, I directed CTP to indicate whether it still sought to compel discovery against Respondent. CTP subsequently withdrew its Motion to Compel Discovery.¹

In accordance with the extended deadlines I established on May 9, 2017, CTP filed its pre-hearing exchange on May 30, 2017. Respondent, however, did not file a pre-hearing exchange. I scheduled a pre-hearing conference which was eventually held on September 7, 2017. In attendance were CTP counsel and Hazem Fadhel, Respondent's principal and representative. During the pre-hearing conference, Mr. Fadhel confirmed that the Answer filed in this matter on behalf of Respondent still reflected Respondent's position. Mr. Fadhel also indicated that Respondent did not intend to present exhibits or witness testimony in this case.

The parties agreed that a hearing was not necessary in this matter and consented to a decision on the record. CTP indicated that it would stand on the arguments submitted in its pre-hearing exchange. I afforded Respondent the opportunity to file its arguments and any documents in support of its position by October 27, 2017. Respondent did not file any arguments or documentation. On November 9, 2017, CTP counsel indicated via e-mail that CTP did not intend to file a reply. *See* Docket No. 35.

II. A Decision on the Record Is Appropriate.

The parties agreed at the September 7, 2017, pre-hearing conference that a decision on the record is appropriate in this matter. As Respondent has not indicated any objection to CTP's exhibits, I now admit CTP Exhibits 1 through 37 into the record.

III. Discussion.

Respondent has not provided any arguments disputing the allegations made in CTP's Complaint beyond the blanket denials found in its Answer.² Nor has it submitted exhibits or witness testimony pertaining to liability or mitigating

¹ Because CTP withdrew its Motion to Compel, I deny its Motion to Impose Sanctions as moot, since it was based on Respondent's failure to comply with the Motion to Compel.

² Respondent's then-legal counsel responded to paragraphs 9 through 11 of the Complaint stating "Respondent is without sufficient information to either admit or deny the allegations at Paragraph[s 9 through 11] and, therefore, denies same, including all inferences and conclusions sought to be drawn therefrom." Answer at 4.

factors. Accordingly, I find the record establishes by preponderance of the evidence that:

- Respondent owns Bruce Discount Tobacco / Tobacco for Less, an establishment that sells tobacco products and is located at 100 South Pontotoc Road, Bruce, Mississippi 38915. Complaint ¶¶ 6-7.
- During an inspection of Respondent’s establishment on October 13, 2014, at approximately 2:47 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Marlboro Menthol cigarettes” The inspector also documented that “the minor’s identification was not verified before the sale” *Id.* at ¶ 10.
- On October 30, 2014, CTP issued a Warning Letter to Respondent regarding the inspector’s documented violations from October 13, 2014. The letter explained that the documented violations constituted violations of regulations, and that the named violations were 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 violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. *Id.* at ¶¶ 10-11.
- During a subsequent inspection of Respondent’s establishment on January 19, 2016, at approximately 3:30 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Newport Non-Menthol Box cigarettes . . . [.]” The inspector also documented that “the minor’s identification was not verified before the sale” *Id.* at ¶ 8.

These facts establish that Respondent is liable under the Act, which 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 applicable regulations prohibit the sale of cigarettes to any person younger than 18 years of age, and 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(a)(1), 1140.14(a)(2)(i).

I find Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on October 13, 2014, and January 19, 2016. On those dates, 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(a)(2)(i). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

Respondent did not submit any evidence concerning factors that could mitigate the penalty, despite being given numerous opportunities to do so. Respondent instead alleged only that:

Respondent specifically denies that Petitioner is entitled to any recovery from Respondent, or, in the alternative, Respondent would submit that the proposed penalty should be reduced

* * * * *

Respondent is a small, locally owned business with limited finances and, therefore, has a limited ability to satisfy the judgment as proposed by Petitioner

See Answer at 5. These unsupported statements are insufficient, and even if taken at face value, the latter claim does not establish Respondent cannot pay a \$550 fine. Respondent has failed to submit any evidence that would allow me to consider its ability to pay the penalty sought or any other mitigating statutory factors. *See* 21 U.S.C. § 333(f)(5)(B). Accordingly, I find the \$550 penalty amount sought by CTP to be appropriate.

ORDER

For the reasons discussed above, I enter judgment in the amount of \$550 against Respondent Bruce Tobacco for Less LLC d/b/a Bruce Discount Tobacco / Tobacco for Less. 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