Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Thirsty's, LLC

d/b/a Thirsty's,

Respondent

FDA Docket No. FDA-2018-H-0545

CRD Docket No. T-18-1180

Decision No. TB2834

Date: June 26, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

Found:

1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), (a)(2)(i) and (a)(3), as charged in the Complaint;
2) Respondent committed at least five violations in a 36-month period as set forth hereinabove; and
3) Respondent is hereby assessed a civil penalty in the amount of $5,591.

Glossary:

ALJ	administrative law judge[1]
CMP	civil money penalty
CTP/Complainant	Center for Tobacco Products
DJ	Default Judgment
FDCA	Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9)
DN	UPS Delivery Notification
FDA	Food and Drug Administration
HHS	Dept. of Health and Human Services
OSC	Order to Show Cause
POS	UPS Proof of Service
SOP	Service of Process
Respondent	Thirsty's, LLC d/b/a Thirsty's
TCA	The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)

I. JURISDICTION

I have jurisdiction to hear this case pursuant to my appointment by the Secretary of Health and Human Services and my authority under the Administrative Procedure Act (5 U.S.C. §§ 554-556), 5 U.S.C.A. § 3106, 21 U.S.C. § 333(f)(5), 5 C.F.R. §§ 930.201 *et seq*. and 21 C.F.R. Part 17.[2]

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint on February 8, 2018, alleging that FDA documented at least five violations within a 36-month period.

[1] *See* 5 C.F.R. § 930.204.

[2] *See also Butz v. Economou*, 438 U.S. 478 at 513, 98 S.Ct. 2894, 57 L.Ed.2d 895 (1978); *Marshall v. Jerrico, Inc*., 446 U.S. 238 (1980); *Federal Maritime Com'n v. South Carolina State Ports Authority*, 535 U.S. 743, 744 (2002).

Thirsty's, LLC d/b/a Thirsty's (Respondent or Thirsty's) was served with process on February 7, 2018, by United Parcel Service. Respondent timely filed an answer on February 16, 2018.

On February 28, 2018, I issued an Acknowledgment and Pre-Hearing Order (Pre-Hearing Order) in which I set a schedule for exchanges of evidence and argument. Pursuant to that order, CTP served Respondent with a Request for Production of Documents on March 6, 2018. Respondent had until March 17, 2018, to file a motion for a protective order or until April 5, 2018, to provide responsive documents. 21 C.F.R. § 17.23(a), (d); Pre-Hearing Order ¶ 3. On April 11, 2018, CTP filed a Motion to Compel Discovery in which CTP averred that Respondent failed to respond to its Request for Production of Documents in its entirety. Respondent did not file a response to CTP's Motion to Compel Discovery.

On April 23, 2018, I issued an Order Denying Motion to Compel Discovery and Order to Show Cause to Respondent. I explained that Respondent failed to comply with the procedural rules in responding to CTP's Request for Production of Documents and the procedures and directives named in my Pre-Hearing Order and in 21 C.F.R. Part 17. I construed CTP's Motion to Compel Discovery as a request for an Order to Show Cause and instructed Respondent to show cause why I should not strike its answer as a sanction for failing to comply with my orders, rules and procedures governing the proceeding. I warned:

> Failure to comply **will result in sanctions**, which may include striking Respondent's answer resulting in 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. 21 C.F.R. § 17.35.

April 23, 2018 Order (Emphasis in original).

I ordered Respondent to show cause no later than April 30, 2018, why I should not strike its answer as a sanction for failing to comply with my orders, rules and procedures governing the proceeding. *Id.*, *citing* 21 C.F.R. § 17.35.

III. STRIKING RESPONDENT'S ANSWER

Pursuant to 21 C.F.R. § 17.35(a), I may sanction a person, including any party or counsel for:

> (1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;
>
> (2) Failing to prosecute or defend an action; or
>
> (3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

Here, Respondent failed to comply with my February 28, 2018, Acknowledgment and Pre-Hearing Order. Respondent did not file a response to CTP's Motion to Compel Discovery. Respondent failed to comply with my April 23, 2018, Order Denying Motion to Compel Discovery and Order to Show Cause to Respondent requiring Respondent to show cause. Respondent has failed to comply with my orders and procedures governing this proceeding and failed to defend its actions. Respondent's misconduct has interfered

with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a). I find sanctions are appropriate pursuant to 21 C.F.R. § 17.35(a).

The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply. 21 C.F.R. § 17.35(b). I find and conclude that Respondent's misconduct is sufficient to warrant striking the answer and issuing a decision without further proceedings. 21 C.F.R. § 17.35(c); *see* 21 C.F.R. § 17.11(a).

IV. BURDEN OF PROOF

CTP as the petitioning party has the burden of proof. 21 C.F.R. § 17.33.

V. LAW

21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), (a)(2)(i) and (a)(3).

VI. ISSUE

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), (a)(2)(i) and (a)(3), as alleged in the complaint?

VII. DEFAULT

I find Respondent was served and is subject to the jurisdiction of this forum, as established by the UPS Delivery Notification and Notice of Filing filed by CTP and by Respondent's Answer seeking relief.

Striking Respondent's Answer leaves the complaint unanswered.

It is Respondent's right to participate in the legal process.

It is Respondent's right to request a hearing or to waive a hearing.

I find Respondent waived its right to a hearing pursuant to 21 C.F.R. § 17.11(b).

VIII. ALLEGATIONS

A. Agency's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Thirsty's, located at 318 4th Street Northeast, Devils Lake, North Dakota 58301. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

CTP's complaint alleged that on May 28, 2015, CTP issued a Warning Letter to Respondent, alleging that Respondent committed the following violations:

a. Selling cigarettes to a minor, in 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 21, 2015, at approximately 4:23 PM;

b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on February 21, 2015, at approximately 4:23 PM; and

c. Using a vending machine in a non-exempt facility, in violation of 21 C.F.R. § 1140.14(a)(3). Specifically, on February 21, 2015, a person younger than 18 years of age was able to enter the establishment and purchase Marlboro

cigarettes from the vending machine. Therefore, this facility does not qualify as one where minors are not permitted to enter at any time.

CTP's complaint further alleged that on July 6, 2017, CTP issued a second Warning Letter to Respondent, alleging that Respondent committed the following violations:

a. Selling cigarettes to a minor, in 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 USA Gold Menthol Gold 100s cigarettes from a vending machine in Respondent's establishment on April 13, 2017, at approximately 11:00 AM;

b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on April 13, 2017, at approximately 11:00 AM; and

c. Using a vending machine in a non-exempt facility, in violation of 21 C.F.R. § 1140.14(a)(3). Specifically, on April 13, 2017, a person younger than 18 years of age was able to enter the establishment and purchase USA Gold Menthol Gold 100's cigarettes from the vending machine. Therefore, this facility does not qualify as one where minors are not permitted to enter at any time.

Because no opportunity for a hearing was provided before the warning letters were

issued, Respondent had a right to challenge the allegations in the warning letters in the instant case. *See Orton Motor Co. d/b/a Orton's Bagley v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).

Further, during an inspection of Thirsty's conducted on January 12, 2018, an FDA-commissioned inspector documented the following violations:

a. Selling tobacco products to a minor, in 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 USA Gold Blue 100s cigarettes from a vending machine in Respondent's establishment on January 12, 2018, at approximately 5:26 PM;

b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on January 12, 2018, at approximately 5:26 PM; and

c. Using a vending machine in a non-exempt facility, in violation of 21 C.F.R. § 1140.14(a)(3). Specifically, on January 12, 2018, a person younger than 18 years of age was able to enter the establishment and purchase USA Gold Blue 100s cigarettes from the vending machine. Therefore, this facility does not qualify as one where minors are not permitted to enter at any time.

B. Respondent's recitation of facts

I struck Respondent's Answer from the record. 21 C.F.R. § 17.35(a).

Accordingly, Respondent filed no responsive pleadings that I may consider.

C. Violations

I find and conclude Respondent committed at least five violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), (a)(2)(i) and (a)(3), within a 36-month period as set forth in the Complaint.

Under the current FDA policy, the violations described in the Complaint counts as at least five violations for purposes of computing the civil money penalty in the instant case.

I find and conclude Respondent committed at least five violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), (a)(2)(i) and (a)(3) within a 36-month period as set forth in the Complaint.

IX. FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

The "relevant statute" in this case is actually a combination of statutes and regulations: The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (TCA), amended the Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) (FDCA) and created a new subchapter of that Act that dealt exclusively with tobacco products, (21 U.S.C. §§ 387-387u), and it also modified other parts of the FDCA explicitly to include tobacco products among the regulated products whose misbranding can give rise to civil, and in some cases criminal, liability. The 2009 amendments to the FDCA contained within the TCA also charged the Secretary of Health and Human Services with, among other things, creating regulations to govern tobacco

sales. The Secretary's regulations on tobacco products appear in Part 1140 of title 21, Code of Federal Regulations.

Under the FDCA, "[a] tobacco product shall be deemed to be misbranded if, in the case of any tobacco product sold or offered for sale in any State, it is sold or distributed in violation of regulations prescribed under section 387f(d)." 21 U.S.C. § 387c(a)(7)(B) (2012). Section 387 a-1 directed FDA to re-issue, with some modifications, regulations previously passed in 1996. 21 U.S.C. § 387 a-1(a)(2012). These regulations were passed pursuant to section 387f(d), which authorizes FDA to promulgate regulations on the sale and distribution of tobacco products; 75 Fed. Reg. 13,225 (March 19, 2010), codified at 21 C.F.R. Part 1140 (2015); 21 U.S.C. § 387f(d)(1) (2012). Accordingly, 21 C.F.R. § 1140.1(b) provides that "failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act."

Under 21 U.S.C. § 331(k), "[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded" is a prohibited act under 21 U.S.C. § 331. Thus, when a Retailer such as Respondent misbrands a tobacco product by violating a requirement of 21 C.F.R. Part 1140, that misbranding in turn violates the FDCA, specifically 21 U.S.C. § 331(k). FDA may seek a civil money penalty from "any person who violates a requirement of this chapter which relates to

tobacco products." 21 U.S.C. § 333(f)(9)(A) (2012). Penalties are set by 21 U.S.C. § 333 note and 21 C.F.R. § 17.2.

A. FDA general policy for counting violations

Under current FDA policy, the first time FDA finds violations of 21 C.F.R. Part 1140 at an establishment, FDA only counts one violation regardless of the number of specific regulatory requirements that were actually violated, but if FDA finds violations on subsequent occasions, it will count violations of specific regulatory requirements individually in computing any civil money penalty sought. This policy is set forth in detail, with examples to illustrate, at *U.S. Food & Drug Admin., Guidance for Industry and FDA Staff, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions (Revised) (2016), available at http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf* [hereinafter *Guidance for Industry*], at 13-14. So, for instance, if a retailer sells a tobacco product on a particular occasion to a minor without checking for photographic identification, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i), this will count as two separate violations for purposes of computing the civil money penalty, unless it is the first time violations were observed at that particular establishment. This policy of counting violations has been determined by the HHS Departmental Appeals Board to be consistent with the language of the FDCA and its implementing regulations. *See Orton Motor Co. d/b/a Orton's Bagley v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).

B. Violations counted in this case

According to current FDA policy, it counts the violations observed during the initial inspection on February 21, 2015 (citing sale to a minor, failure to verify identification, and an impermissible vending machine) as one violation, even though Respondent violated three specific regulatory requirements. Additionally, FDA would count the violations observed during the subsequent April 13, 2017 and January 12, 2018 inspections (sale to a minor, failure to verify identification, and an impermissible vending machine observed during each inspection), as six additional violations. CTP could count seven violations when computing a civil money penalty sought against Respondent.

Although CTP could have counted seven violations when calculating the penalty imposed, it only counted five. CTP did not explain its methodology employed in this case. Nevertheless, it is within CTP's authority to count fewer violations than it cited when imposing a civil money penalty. *Guidance for Industry* at 14 (noting "FDA may count any or all violations" in subsequent inspections).

X. LIABILITY

When a retailer such as Respondent is found to have "misbranded" a tobacco product in interstate commerce, it can be liable to pay a CMP. 21 U.S.C. §§ 331, 333. A retailer facing such a penalty has the right, set out in statute, to a hearing under the Administrative Procedure Act (21 U.S.C. § 333(f)(5)(A)). A retailer can forfeit its rights under the statute and regulations by failing to participate in the process, a failure known as a "default" (21 C.F.R. § 17.11).

As set forth above, it is Respondent's right to decide whether to participate in the legal process. It is Respondent's right to decide to request a hearing and it is Respondent's right to waive a hearing.

I find Respondent, by failing to respond, waived its right to a hearing.

XI. IMPACT OF RESPONDENT'S DEFAULT

When a Respondent defaults by failing to answer the complaint, or respond to a OSC, an ALJ must assume as true all factual allegations in the complaint and issue an initial decision within thirty (30) days of the answer's due date, imposing "the maximum amount of penalties provided for by law for the violations alleged" or "the amount asked for in the complaint, whichever is smaller" if "liability under the relevant statute" is established (21 C.F.R. § 17.11(a)(1) and (2)). *But see* 21 C.F.R. § 17.45 (initial decision must state the "appropriate penalty" and take into account aggravating and mitigating circumstances).

Two aspects of Rule 17.11 are important in default cases.

First, the Complainant benefits from a regulatory presumption (the ALJ shall assume that the facts alleged in the complaint are true) that relieves it from having to put on evidence:

The presumption affords a party, for whose benefit the presumption runs, the luxury of not having to produce specific evidence to establish the point at issue. When the predicate evidence is established that triggers the presumption, the further evidentiary gap is filled by the presumption. *See* 1 Weinstein's Federal Evidence § 301.02[1], at

301-7 (2d ed.1997); 2 McCormick on Evidence § 342, at 450 (John W. Strong ed., 4th ed. 1992). *Routen v. West*, 142 F.3d 1434, 1440 (Fed. Cir. 1998).[3]

Second, as far as the penalty is concerned, my discretion is limited by the language of the regulation. I may not tailor the penalty to address any extenuation or mitigation, for example, nor, because of notice concerns, may I increase the penalty beyond the smaller of (a) the Complainant's request or (b) the maximum penalty authorized by law.

XII. LIABILITY UNDER THE RELEVANT STATUTE

Taking the CTP's allegations as set forth in the complaint as true, the next step is whether the allegations make out "liability under the relevant statute" (21 C.F.R. § 17.11(a)).

Based on Respondent's failure to answer I assume all the allegations in the complaint to be true.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), in that a person younger than 18 years of age was able to purchase cigarettes on February 21, 2015, April 13, 2017, and January 12, 2018.

---

[3] However, when the opposing party puts in proof to the contrary of that provided by the presumption, and that proof meets the requisite level, the presumption disappears. *See Texas Dept. of Community Affairs v. Burdine*, 450 U.S. 248, 254-55, 101 S. Ct. 1089, 1094-95, 67 L. Ed. 2d 207 (1981); *A.C. Aukerman*, 960 F.2d at 1037 ("[A] presumption . . . completely vanishes upon the introduction of evidence sufficient to support a finding of the nonexistence of the presumed fact."); *see also Weinstein's Federal Evidence* § 301App.100, at 301App.-13 (explaining that in the "bursting bubble" theory once the presumption is overcome, then it disappears from the case); 9 *Wigmore on Evidence* § 2487, at 295-96 (Chadbourn rev. 1981). *See generally* Charles V. Laughlin, *In Support of the Thayer Theory of Presumptions*, 52 Mich. L. Rev. 195 (1953). *Routen v. West*, 142 F.3d 1434, 1440 (Fed. Cir. 1998).

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i), on those same dates in that 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.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(3), on those same dates in that Respondent also violated the requirement that retailers sell cigarettes only in direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine) in a non-exempt facility.[4]

It is permissible for FDA to count conduct set forth above on February 21, 2015, April 13, 2017, and January 12, 2018, as five violations.

XIII. PENALTY

There being liability under the relevant statute, I must now determine the amount of penalty to impose. My discretion regarding a penalty is constrained by regulation. I must impose either the maximum amount permitted by law or the amount requested by the Center, whichever is lower. 21 C.F.R. § 17.11(a)(1), (a)(2).

In terms of specific punishments available, the legislation that provides the basis for assessing civil monetary penalties divides retailers into two categories: those that

[4] An exempt facility is one in which the "retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time." 21 C.F.R. § 1140.16(c)(2)(ii).

have "an approved training program" and those that do not. Retailers with an approved program face no more than a warning letter for their first violation; retailers without such a program begin paying monetary penalties with their first. TCA § 103(q)(2), 123 Stat. 1839, *codified at* 21 U.S.C. § 333 note. *See* 21 C.F.R. § 17.2. The FDA has informed the regulated public that "at this time, and until FDA issues regulations setting the standards for an approved training program, all applicable CMPs will proceed under the reduced penalty schedule." FDA Regulatory Enforcement Manual, Aug. 2015, ¶ 5-8-1. Because of this reasonable exercise of discretion, the starting point for punishments and the rate at which they mount are clear – the lower and slower schedules.

XIV. MITIGATION

It is incumbent upon Respondent to present any factors that could result in mitigation of CTP's proposed penalty. Specifically, it is Respondent's burden to provide mitigating evidence. In a default, Respondent has failed to participate and has failed to present any evidence regarding potential mitigation. Accordingly, I have no reason to mitigate the penalty.

XV. CONCLUSION

Respondent committed at least five violations in a 36-month period and so, Respondent is liable for a civil money penalty of $5,591. *See* 21 C.F.R. § 17.2.

WHEREFORE, evidence having read and considered it be and is hereby ORDERED as follows:

a. I find Respondent has been served with process herein and is subject to this forum.

b. I find Respondent failed to respond to my Order to Show Cause.

c. I find Respondent failed to comply with my orders and procedures governing this proceeding and failed to defend its actions, constituting misconduct that has interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a).

d. I find Respondent's misconduct warrants striking its answer as a sanction. 21 C.F.R. § 17.35(c).

e. I find striking Respondent's answer leaves the complaint unanswered. 21 C.F.R. § 17.11.

f. I find Respondent is in default.

g. I assume the facts alleged in the complaint to be true. 21 C.F.R. § 17.11.

h. I find the facts set forth in the complaint establish liability under the relevant statute.

i. I assess a monetary penalty in the amount of $5,591.

_____/s/_____
Richard C. Goodwin
U.S. Administrative Law Judge