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

Center for Tobacco Products,
Complainant

v.

The Phoenician, Inc.
d/b/a Phoenician Market,
Respondent

FDA Docket No. FDA-2017-H-0423
CRD Docket No. T-17-1845

Decision No. TB2022

Date: October 5, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

Found:

1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i)[1] as charged in the complaint; and
2) Respondent committed three violations in a 24-month period as set forth hereinabove.
3) Respondent is hereby assessed a civil penalty in the amount of $550.

Glossary:

ALJ	administrative law judge[2]
CMP	civil money penalty
CTP/Complainant	Center for Tobacco Products

[1] On August 8, 2016, citations to certain tobacco regulations were renumbered but remained unchanged in substance. Relevant here, 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1), were renumbered to 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i), respectively. *See* https://federalregister.gov/a/2016-10685. In this decision I cite to the regulations as they currently appear.

[2] *See* 5 C.F.R. § 930.204.

DJ	Default Judgment
FDCA	Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9)
FDA	Food and Drug Administration
HHS	Dept. of Health and Human Services
POS	UPS Proof of Service
Respondent	The Phoenician, Inc. d/b/a Phoenician Market
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.[3]

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint on February 3, 2017, alleging that FDA documented three violations within a 24-month period.

The Phoenician, Inc. d/b/a Phoenician Market (Respondent or Phoenician Market) was served with process on February 2, 2017, by United Parcel Service. Respondent filed an Answer on March 1, 2017. On March 6, 2017, I ordered the parties to discuss settling the case and informed the parties that if settlement did not conclude

[3] *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).

during that time, I would set benchmarks for proceeding. The parties failed to settle the case.

On May 8, 2017, I issued an Acknowledgment and 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 June 5, 2017. Respondent had until July 5, 2017, to provide responsive documents or to file a motion for a protective order. Respondent failed to comply with my orders and schedule for proceedings. On July 14, 2017, CTP filed a Motion to Compel Discovery and a Motion to Extend Deadlines in which CTP averred that Respondent failed to comply with its request for production of documents. Respondent did not file a response to CTP's Motion to Compel Discovery.

On August 15, 2017, I issued an Order to Compel Discovery, in which I ordered Respondent to comply with CTP's Request for Production of Documents by August 24, 2017, and for Respondent to show cause on or before August 24, 2017, why default judgment should not be entered against it for failure to comply with the procedural rules and respond to CTP's pleadings. I warned that failure to comply will result in sanctions which may include issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Compliant and imposing a civil money penalty pursuant to 21 C.F.R. § 17.35. Respondent failed to file any responsive pleadings to my August 15, 2017, order directing Respondent to show cause.

On September 12, 2017, CTP filed a Motion to Impose Sanctions against Respondent asserting that Respondent did not comply with my August 15, 2017, order to

produce the requested documents. In its motion, CTP asked that I strike Respondent's Answer and issue a Default Judgment against Respondent as a sanction for failure to comply with my orders. Respondent did not file a response to CTP's Motion to Impose Sanctions.

On September 14, 2017, I issued an Order to Show Cause to Respondent. I explained that Respondent failed to comply with my orders, rules and procedures governing this proceeding, that its failings constitute misconduct that interferes with the speed, orderly or fair conduct of this proceeding, actions which subject it to sanctions pursuant to 21 C.F.R. § 17.35. I ordered Respondent to show cause on or before close of business September 19, 2017, why I should not strike Respondent's answer and enter Judgment of Default in favor of the Complainant. 21 C.F.R. §§ 17.11, 17.35. I warned that if Respondent failed to show cause, I would strike its answer pursuant to 21 C.F.R. § 17.35 and enter Judgment of Default pursuant to 21 C.F.R. § 17.11. Respondent failed to file a response to my Order to Show Cause.

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 May 8, 2017, Acknowledgment and Pre-Hearing Order. Respondent did not file a response to CTP's Motion to Compel Discovery. Respondent failed to comply with my August 15, 2017, Order to Compel Discovery requiring Respondent to show cause. Respondent did not file a response to CTP's Motion to Impose Sanctions. Respondent failed to comply with my September 14, 2017, Order to Show Cause. Respondent has failed to comply with my orders and procedures governing this proceeding which constitutes misconduct that has interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a)(1), (a)(3). I find sanctions are appropriate under 21 C.F.R. § 17.35(a)(1) and (a)(3).

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 sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

IV. BURDEN OF PROOF

The Center for Tobacco Products (CTP/Complainant) 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) and 1140.14(a)(2)(i).

VI. ISSUE

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

VII. DEFAULT

I find there is a presumption that Respondent was served, which Respondent has failed to rebut, and that Respondent is subject to the jurisdiction of this forum, as established by the Notice of Filing and attachments filed by CTP.

Striking Respondent's Answer leaves the Complaint unanswered.

In my September 14, 2017 Order to Show Cause I ordered Respondent to Show Cause on or before close of business September 19, 2017, why I should not strike Respondent's answer and enter Judgment of Default in favor of the Complainant. 21 C.F.R. §§ 17.11, 17.35.

Respondent failed to file any pleading in response to my September 14, 2017, Order to Show Cause. Pursuant to 21 C.F.R. §§ 17.35(c)(3), 17.11(a), I struck Respondent's Answer as a sanction.

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.

By failing to file a response pleading, 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 Phoenician Market, located at 608 Georges Road, North Brunswick, New Jersey 08902. 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 October 29, 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). Specifically, a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on October 20, 2015, at approximately 3:44 PM; and

b. Failing to verify the age of a person purchasing cigarettes by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(b)(1). Specifically, the minor's identification was not verified before the sale, as detailed above, on October 20, 2015, at approximately 3:44 PM.

Because no opportunity for a hearing was provided before the Warning Letter was issued, Respondent had a right to challenge the allegations in the Warning Letter in the instant case. *See CTP v. Orton Motor Company*, Departmental Appeals Board Decision number 2717 of June 30, 2016, at 25.

Further, during an inspection of Phoenician Market conducted on July 16, 2016, an FDA-commissioned inspector documented 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 Newport Box cigarettes on July 16, 2016, at approximately 11:13 AM; and

b. Failing to verify the age of a person purchasing cigarettes 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 July 16, 2016, at approximately 11:13 AM.

B. Respondent's recitation of facts

Respondent filed no responsive pleadings.

As Respondent's Answer has been stricken from the record, I find and conclude that Respondent waived the right to challenge the allegations in the Complaint.

I assume those allegations set forth in the Complaint to be true.

Therefore, under FDA's current policy, the violations described in the Complaint counts as three violations for purposes of computing the civil money penalty in the instant case. *See Guidance for Industry*, at 13-14.

I find and conclude Respondent committed three violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i) within a 24-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. 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 CTP v. Orton Motor Company*, Departmental Appeals Board Decision number 2717, of June 30, 2016.

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 responding to

an Order to Show Cause, an ALJ must assume as true all factual allegations in the complaint and issue an initial decision within 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).[4]

[4] 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 § 301 App. 100, at 301 App.-13 (explaining that in the "bursting bubble" theory once the presumption is overcome, then it disappears from the case);

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 October 20, 2015, and July 16, 2016.

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.

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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, at 1440 (1998).

The conduct set forth above on October 20, 2015, and July 16, 2016, counts as three violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-14.

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 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

Because Respondent is found to be in default I am required to impose the maximum amount of penalties provided for by law for the violations alleged. Therefore, no mitigation is considered.

XV. CONCLUSION

Respondent committed three violations in a 24-month period and so, Respondent is liable for a civil money penalty of $550. *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 comply with my orders and procedures governing this proceeding that constitutes misconduct interfering with the speedy, orderly, or fair conduct of this proceeding, as set forth hereinabove. 21 C.F.R. § 17.35(a)(1), (a)(3).
c. I find Respondent's misconduct warrants striking its answer. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).
d. I find that striking Respondent's answer leaves the complaint unanswered.
e. I find Respondent is in default.
f. I assume the facts alleged in the complaint to be true.
g. I find the facts set forth in the complaint establish liability under the relevant statute.
h. I assess a monetary penalty in the amount of $550.

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