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

Center for Tobacco Products,
Complainant,

v.

Asza 3 Inc.
d/b/a 7-Eleven Store 27216B,
Respondent.

FDA Docket No. FDA-2018-H-0262
CRD Docket No. T-18-967

Decision No. TB3181

Date: October 18, 2018

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) as charged in the Complaint; and
2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) as charged in the prior Complaint; and
3) Respondent committed five (5) violations in a 36-month period as set forth hereinabove.
4) 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

[1] *See* 5 C.F.R. § 930.204.

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 Granting Motion for Default and Order to Show Cause to Respondent
POS	UPS Proof of Service
SOP	Service of Process
Respondent	Asza 3 Inc. d/b/a 7-Eleven Store 27216B
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 January 23, 2018, alleging that FDA documented five (5) violations within a 36-month period.

Asza 3 Inc. d/b/a 7-Eleven Store 27216B (Respondent or 7-Eleven Store 27216B) was served with process on January 22, 2018 by United Parcel Service. Respondent filed an Answer on February 14, 2018. On March 6, 2018, I issued an Acknowledgement and

[2] *See also Butz v. Economou*, 438 U.S. 478 at 513 (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).

Pre-Hearing Order (APHO) setting a schedule for filings and procedures. Pursuant to my APHO, CTP served Respondent's counsel with a Request for Production of Documents on March 28, 2018.

On May 3, 2018, CTP filed Motions to Compel Discovery and Extend Deadlines averring Respondent failed to comply with its request for production of documents. On May 29, 2018, I issued an Order giving Respondent until June 14, 2018 to file a response to CTP's Motion to Compel Discovery. In the Order, I also extended the simultaneous pre-hearing exchange deadlines. Respondent did not file a response to CTP's Motion to Compel. On June 18, 2018, I issued an Order granting CTP's Motion to Compel Discovery, and ordered Respondent to comply with CTP's Request for Production of Documents by July 5, 2018.[3] I further warned Respondent "[f]ailure to do so may result in sanctions, including 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."

On July 10, 2018, CTP filed a Motion to Impose Sanctions against Respondent asserting that Respondent failed to respond to CTP's request for production of documents or comply with my June 18, 2018 Order. 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.[4] On July 12, 2018, I issued an Order, directing

[3] My June 18, 2018 Order also extended the simultaneous pre-hearing exchange deadline to August 1, 2018.

[4] Contemporaneously with its Motion to Impose Sanctions, CTP moved to stay all deadlines.

Respondent to comply with CTP's Request for Production of Documents by July 23, 2018. Again I warned Respondent that: "Failure to comply may result in sanctions, including 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."[5,6]

On July 24, 2018, CTP filed an Unopposed Motion to Extend Deadlines and Notice of Pending Settlement, requesting that all deadlines, including the pre-hearing exchange deadline scheduled for August 1, 2018, be extended by 30 days. On July 26, 2018, I issued an Order which stayed the case for a period of 45 days.

On September 10, 2018, CTP filed a Motion for Default Judgment averring Respondent failed to: 1) comply with CTP's request for production of documents; 2) respond to CTP's Motion to Compel; and 3) comply with the ALJ's June 18, 2018 and July 12, 2018 Orders. 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. On September 14, 2018, I issued an Order Granting Motion for Default and Order to Show Cause to Respondent directing Respondent to show cause no later than September 19, 2018 why a default judgment should not be entered in favor of CTP.

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[5] In my July 12, 2018 Order, I explained: "In sum, CTP has filed a Motion to Extend Deadlines based on Respondent's failure to comply with the rules and my Orders. Based on [CTP's] representations, CTP should have filed a Motion for Default Judgment based on Respondent's failure to comply. I will deny CTP's request to extend deadlines and treat CTP's Motion to Extend Deadlines as a Motion for Default Judgment, denying the request for extension and instructing Respondent to comply as set forth below or risk the consequences of its failure to comply."

[6] In the July 12, 2018 Order, I inadvertently referred to "CTP's Motion to Stay Deadlines" as "CTP's Motion to Extend Deadlines."

To date, Respondent has failed to respond.

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.

In this case, Respondent failed to comply with my orders and procedures governing this proceeding.

III. STRIKING RESPONDENT'S ANSWER

Respondent failed to comply with my March 6, 2018 APHO, did not respond to the May 29, 2018 Order, failed to comply with my June 18, 2018 Order Granting Motion to Compel, did not respond to CTP's July 10, 2018 Motion to Impose Sanctions, and failed to comply with my September 14, 2018 OSC. In fact, Respondent has not made any contact with this Court since Respondent's February 14, 2018 Answer.

Due to Respondent's noncompliance, I am striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's Complaint to be true. 21 C.F.R. §§ 17.35(c)(3), 17.11(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). Respondent failed to comply with my March 6, 2018 APHO, and my May 29, 2018, June 18, 2018, July 12, 2018, and September 14, 2018 Orders.

I find and conclude Respondent's repeated failure to comply with my orders is sufficiently egregious to warrant striking Respondent's Answer and issuing a decision without further proceedings. 21 C.F.R. §§ 17.35(b), (c)(3), 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) 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 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.

Striking Respondent's Answer leaves the Complaint unanswered.

My June 18, 2018 Order is incorporated herein by reference. My Order instructed Respondent to comply with CTP's request for document production on or before close of business on July 5, 2018. Respondent failed to file any pleading in response or otherwise comply with my June 18, 2018 Order.

Pursuant to 21 C.F.R. § 17.35(c)(3), 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.

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 owns an establishment, doing business under the name 7-Eleven Store 27216B, located at 6845 North 22nd Street, Tampa, Florida 33610. Respondent's establishment receives tobacco products in interstate commerce and holds them for sale after shipment in interstate commerce.

During an inspection of 7-Eleven Store 27216B conducted on December 26, 2017, 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 Marlboro Gold Pack cigarettes on December 26, 2017, at approximately 1:47 PM; and

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 December 26, 2017, at approximately 1:47 PM.

B. Respondent's recitation of facts

I struck Respondent's Answer filed on February 14, 2018.

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

IX. PRIOR VIOLATIONS

On May 16, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-4027, FDA Docket Number FDA-2017-H-2847, against Respondent for three (3) violations of 21 C.F.R. pt. 1140. CTP alleged those violations to have occurred at Respondent's business establishment, 6845 North 22nd Street, Tampa, FL 33610, on November 5, 2016, and January 25, 2017.

The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon a monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions."

I find and conclude Respondent committed five (5) 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 36-month period as set forth in the Complaint.

X. 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 387a-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 (Mar. 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 Orton Motor Co. d/b/a Orton's Bagley v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).

XI. 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.

In that I have stricken Respondent's answer from the record as a sanction for failing to respond to my orders and directives, I find Respondent has failed to answer the Complaint and, therefore, has waived its right to a hearing.

XII. IMPACT OF RESPONDENT'S DEFAULT

When a Respondent defaults by failing to answer the Complaint, or respond to an 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), (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).[7]

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.

[7] 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).

XIII. 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 or smokeless tobacco on November 5, 2016, January 25, 2017, and December 26, 2017.

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 January 25, 2017, and December 26, 2017 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 or smokeless tobacco purchasers are younger than 18 years of age.

The conduct set forth above on November 5, 2016, January 25, 2017, and December 26, 2017 counts as five (5) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-14.

XIV. 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.

XV. 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.

XVI. CONCLUSION

Respondent committed five (5) 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 June 18, 2018 Order.
c. I strike Respondent's Answer filed on February 14, 2018 as a sanction pursuant to 21 C.F.R. §§ 17.35(c)(3).
d. I find Respondent is in default.
e. I find the facts alleged in the Complaint to be true.
f. I find the facts set forth in the Complaint establish liability under the relevant statute.
g. I assess a monetary penalty in the amount of $5,591.

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