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

Center for Tobacco Products,
Complainant

v.

M and K Food Mart Inc.
d/b/a Sphinx,
Respondent

FDA Docket No. FDA-2015-H-4095
CRD Docket No. T-17-390

Decision No. TB1951

Date: October 10, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

Found:

1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1) as charged in the complaint; and
2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1) 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 $5,000.

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

[1] *See* 5 C.F.R. § 930.204.

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	M and K Food Mart Inc. d/b/a Sphinx
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 November 25, 2016, alleging that FDA documented five (5) violations within a 36-month period.

M and K Food Mart Inc. d/b/a Sphinx (Respondent or Sphinx) was served with process on November 17, 2015 by United Parcel Service (UPS). Respondent filed an Answer to the Complaint dated December 16, 2015.

On May 11, 2016, I issued a Procedural Order which established deadlines for the parties pre-hearing submissions. On October 5, 2016, the parties filed a timely Joint Status Report advising that settlement had been reached in this case. The parties

[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).

requested a stay of the proceedings pending Respondent's payment of the settlement amount by December 15, 2016. On October 7, 2016, I issued an Order granting a stay through January 16, 2017.

On January 17, 2017, the parties filed a second timely Joint Status Report requesting an extension of the stay, due to delay of payment of the settlement amount. By Order dated February 7, 2017, I granted the parties' request and extended the stay through February 16, 2017.

On February 16, 2017, CTP filed a timely Status Report. In the Status Report, CTP requested that I re-establish the pre-hearing benchmarks in the case. CTP advised, among other things:

> As of the date of this filing, the Respondent has not paid the agreed upon settlement amount. On January 31, 2017, February 10, 2017, and February 15, 2017, CTP conversed with counsel for Respondent regarding the status of the case. Respondent's counsel represented that she has been unable to reach Respondent, who remains out of the country . . . .

Based on CTP's representation, I issued an Order on March 15, 2017, granting CTP's request to re-establish all pre-hearing benchmarks. In my Order, a deadline of March 29, 2017 was set for filing a joint status report regarding the status of settlement negotiations and serving requests for document production; a deadline of May 1, 2017 for all pre-hearing exchanges from CTP to Respondent; and a deadline of May 15, 2017 for all pre-hearing exchanges from Respondent to CTP.

On March 29, 2017, the parties filed a Joint Status Report informing me that on March 27, 2017, "CTP spoke with Respondent's counsel, who confirmed that

Respondent was back in the country, and stated that Respondent would honor the settlement agreement and would pay the settlement amount by April 15, 2017."

On April 24, 2017, CTP filed a Motion to Compel Discovery. CTP indicated that Respondent had not responded to the Request for Production of Documents that CTP served on Respondent on July 18, 2016. In an April 26, 2017 letter issued by direction, Respondent was given until May 8, 2017 to file a response to CTP's Motion to Compel Discovery. Respondent failed to file any response to CTP's Motion to Compel Discovery or otherwise respond to the April 26, 2017 letter.

On May 22, 2017, I issued an Order granting CTP's Motion to Compel Discovery and instructing Respondent to comply with CTP's Request for Production of Documents no later than May 30, 2017. In the Order, I warned Respondent that failure to respond may result in sanctions, including the issuance of an Initial Decision and Default Judgment. Respondent did not respond to my May 22, 2017 Order.

On June 15, 2017, CTP filed a Status Report and Motion to Impose Sanctions (Status Report and Motion). The Status Report and Motion stated that Respondent had not complied with my May 22, 2017 Order granting CTP's Motion to Compel Discovery. On June 15, 2017, CTP also filed a Motion to Extend Deadlines. In a June 22, 2017 Order, I denied CTP's Motion to Extend Deadlines, and directed Respondent to comply with CTP's Request for Document Production no later than June 28, 2017. Respondent was again warned that failure to comply may result in the imposition of sanctions, including the issuance of an Initial Decision and Default Judgment. Respondent did not comply with my June 22, 2017 Order, or otherwise comply with CTP's Request for

Document Production. Subsequently, on August 8, 2017, CTP filed the pending Motion to Impose Sanctions and Issue Default Judgment.

III. STRIKING RESPONDENT'S ANSWER

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

Due to Respondent's noncompliance with the April 26, 2017 letter and my May 22, 2017 and June 22, 2017 Orders, CTP's August 8, 2017 Motion to Impose Sanctions is granted. *See* 21 C.F.R. §§ 17.35(a)(1), 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, and I find the failure to comply here sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

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.

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).[3]

VI. ISSUE

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

VII. DEFAULT

I find there is a presumption Respondent was served which Respondent has failed to rebut. I also find that Respondent is subject to the jurisdiction of this forum, as established by the UPS Delivery Notification filed by CTP and Respondent's Answer to CTP's Complaint. The letter dated April 26, 2017, and my Orders dated April 26, 2017, May 22, 2017, and June 22, 2017 are incorporated herein by reference.

The April 26, 2017, letter directed Respondent to file a response to CTP's Motion to Compel Discovery not later than May 8, 2017. My Orders dated May 22, 2017 and June 22, 2017 instructed Respondent to comply with CTP's Request for Production of Documents. The Orders further advised 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

[3] On August 8, 2016, the citations to certain tobacco violations changed. For more information see: https://federalregister.gov/a/2016-10685.

penalty.

Respondent failed to file a responsive pleading to the April 26, 2017 letter or my May 22, 2017 and June 22, 2017 Orders. 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.

I find Respondent, by failing to file a responsive pleading to the April 26, 2017 letter, or comply with my May 22, 2017 and June 22, 2017 Orders, has waived its right to a hearing.

VIII. ALLEGATIONS

A. Agency's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Sphinx, located at 7255 East Jefferson Avenue, Detroit, Michigan 48214. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

During an inspection of Sphinx conducted on July 28, 2015, 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). Specifically, a person younger than l8 years of age was able to purchase a package of Newport Box 100s cigarettes on July 28, 2015, at approximately 12:19 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, in violation of 21 C.F.R. § 1140.14(b)(1). Specifically, the minor's identification was not verified before the sale on July 28, 2015 at approximately 12:19 PM.

B. Prior Violations

On March 9, 2015, CTP initiated a previous civil money penalty action, FDA Docket Number FDA-2015-H-0721, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period. The violations of 21 U.S.C. § 331 that were included when calculating the penalty in the current case, are 21 C.F.R. § 1140.14(a) and 21 C.F.R. § 1140.14(b)(1). CTP alleged those violations to have occurred at Respondent's business establishment, 7255 East Jefferson Avenue, Detroit, Michigan 48214, on May 3, 2014, and October 18, 2014.

An Initial Decision and Default Judgment, was entered by Administrative Law Judge Catherine Ravinski on May 1, 2015, which found that the "all of the violations alleged in the Complaint occurred . . . [.]" The previous action concluded when the Initial Decision and Default Judgment became final on May 31, 2015.

I find and conclude Respondent committed three (3) violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a) and 21 C.F.R. § 1140.14(b)(1) within a twenty-four month period as set forth in the complaint.

VII. 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) and (b)(1), 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 (Appellant Div. June 30, 2016).

IX. 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.

X. 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).[4]

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

[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 § 301App.100, at 301 App.–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).

smaller of (a) the Complainant's request or (b) the maximum penalty authorized by law.

XI. 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) in that a person younger than 18 years of age was able to purchase cigarettes on May 3, 2014, October 18, 2014, and July 28, 2015.

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(b)(1) on May 3, 2014, October 18, 2014, and July 28, 2015 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 purchaser is younger than 18 years of age.

The conduct set forth above on May 3, 2014, October 18, 2014, and July 28, 2015 count as five (5) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-14.

XII. 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.

XIII. 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.

XIV. CONCLUSION

Respondent committed five (5) violations in a 36-month period and so, Respondent is liable for a civil money penalty of $5,000. *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 Orders.
c. I find Respondent is in default.
d. I assume the facts alleged in the complaint to be true.
e. I find the facts set forth in the complaint establish liability under the relevant statute.
f. I assess a monetary penalty in the amount of $5,000.

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