

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

KCP, Inc.  
d/b/a KC Mart 7,

Respondent.

FDA Docket No. FDA-2017-H-6725  
CRD Docket No. T-18-559

Decision No. TB2694

Date: May 3, 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), (b)(1) and (b)(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 (a)(2)(i) as charged in the prior complaint; and
- 3) Respondent committed six violations in a 48-month period as set forth hereinabove.
- 4) Respondent is hereby assessed a civil penalty in the amount of \$11,182.

Glossary:

ALJ	administrative law judge <sup>1</sup>
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	KCP, Inc. d/b/a KC Mart 7
TCA	The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)(TCA)

## 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.<sup>2</sup>

## II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a complaint on December 7, 2017, alleging that FDA documented six violations within a 48-month period.

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<sup>1</sup> See 5 C.F.R. § 930.204.

<sup>2</sup> 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).

KCP, Inc. d/b/a KC Mart 7 (Respondent or KC Mart 7) was served with process on December 6, 2017, by United Parcel Service. Respondent, through counsel, filed an Answer on December 21, 2018.

On December 29, 2017, 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 January 11, 2018. Respondent had until January 22, 2018, to file a motion for a protective order or until February 12, 2018, to provide responsive documents. 21 C.F.R. § 17.23(a), (d); Pre-Hearing Order at ¶ 3. On February 26, 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 March 14, 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 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.

March 14, 2018 Order (Emphasis in original).

I ordered Respondent to show cause no later than March 26, 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 December 29, 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 March 14, 2018, Order to 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), (b)(1) and (b)(2)(i).

#### VI. ISSUE

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) and (b)(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 / Certification 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 KC Mart 7, located at 303 Lee Vaughn Road, Simpsonville, South Carolina 29681. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

During an inspection of KC Mart 7 conducted on November 6, 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(b)(1).  
Specifically, a person younger than 18 years of age was able to purchase a package of two Swisher Sweets White Grape cigars on November 6, 2017, at approximately 6:08 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(b)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on November 6, 2017, at approximately 6:08 PM.

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.

IX. PRIOR VIOLATIONS

On May 5, 2017, CTP initiated its most recent civil money penalty action, CRD Docket Number T-17-3850, FDA Docket Number FDA-2017-H-2641,<sup>3</sup> against Respondent for four<sup>4</sup> violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 303 Lee Vaughn Road, Simpsonville, South Carolina 29681, on April 24, 2015, December 28, 2015, and December 29, 2016.

The previous action concluded when an Initial Decision and Default Judgment was entered by Administrative Law Judge, "finding that all of the violations alleged in the Compliant occurred."

I find and conclude Respondent committed six violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), (a)(2)(i), (b)(1) and (b)(2)(i) within a 48-month period as set forth in the complaint.

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<sup>3</sup> See also CRD Docket Number T-16-1048, FDA Docket Number FDA-2016-H-1750.

<sup>4</sup> One violation was documented on April 24, 2015 (sale of cigarettes or smokeless tobacco to a minor), one violation on December 28, 2015 (sale of cigarettes or smokeless tobacco to a minor), and two violations on December 29, 2016 (sale of cigarettes or smokeless tobacco to a minor and failure to verify identification).

## 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 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/Rules/RegulationsGuidance/UCM447310.pdf> [hereinafter *Guidance for Industry*], at 13-14. So, for instance, if a retailer sells a covered tobacco product on a particular occasion to a

minor without checking for photographic identification, in violation of 21 C.F.R. § 1140.14(b)(1) and (b)(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*, Departmental Appeals Board (DAB) No. 2717, at 25 (2016); *pet. for rev. denied*, No. 2018 WL 1386141 (D.C. Cir., Mar. 20, 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.

I find Respondent 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

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), (a)(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).<sup>5</sup>

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<sup>5</sup> 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*

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.

### 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).

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) and (b)(1) in that a person younger than 18 years of age was able to purchase cigarettes, smokeless tobacco, or covered tobacco products on April 24, 2015, December 28, 2015, December 29, 2016, and November 6, 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) and (b)(2)(i) on December 29, 2016, and November 6, 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, smokeless tobacco, or covered tobacco product purchasers are younger than 18 years of age.

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§ 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 (Fed. Cir. 1998).

The conduct set forth above on April 24, 2015, December 28, 2015, December 29, 2016, and November 6, 2017, counts as six violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-15.

#### 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

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 that I may consider regarding potential mitigation.

Accordingly, I have no reason to mitigate the penalty.

XVI. CONCLUSION

Respondent committed six violations in a 48-month period and so, Respondent is liable for a civil money penalty of \$11,182. *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 \$11,182.

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