

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

Center for Tobacco Products,  
Complainant

v.

In Chul Lee and Hye Jung Lee  
d/b/a Parks Place / Shell Food Mart,  
Respondent

FDA Docket No. FDA-2017-H-2280  
CRD Docket No. T-17-3516

Decision No. TB1787

Date: August 22, 2017

**INITIAL DECISION AND DEFAULT JUDGMENT**

Found:

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

Glossary:

ALJ	administrative law judge <sup>1</sup>
CMP	civil money penalty
CTP/Complainant	Center for Tobacco Products
DJ	Default Judgment

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<sup>1</sup> 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 to Show Cause
POS	UPS Proof of Service
SOP	Service of Process
Respondent	In Chul Lee and Hye Jung Lee d/b/a Parks Place / Shell Food Mart
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 April 25, 2017 alleging that FDA documented three violations within a twenty-four month period.

In Chul Lee and Hye Jung Lee d/b/a Parks Place / Shell Food Mart (Respondent or Parks Place / Shell Food Mart) was served with process on April 21, 2017 by United Parcel Service (UPS). Respondent filed an Answer to the Complaint on May 1, 2017.

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<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).

On July 17, 2017, CTP filed a Motion to Extend Deadlines. In its motion, CTP alleged that it “has made multiple attempts to contact the Respondent to discuss this case...[h]owever...CTP has been unable to reach Respondent.” On the aforementioned date CTP also filed a Motion to Compel Discovery, in which it alleged that “CTP sent Respondent a Request for Production of Documents on June 12, 2017...[but] has not received a response to its Request for Production of Documents.”

On July 21, 2017, I issued an Order to Show Cause (OSC) to Respondent<sup>3</sup> that specified that Respondent had “until close of business on July 28, 2017, to Show Cause why a Judgment of Default should not be entered in favor of the Complainant for failing to respond to CTPs Request for Production.” Additionally, in the OSC, CTP was instructed that if Respondent failed to Show Cause as ordered, CTP had “until close of business on August 4, 2017, to file a Motion for Default Judgment or withdraw its case.”

Respondent did not respond to the OSC by the requisite deadline. On July 31, 2017, CTP filed a Motion for Default Judgment. On that same date, CTP also filed a second Motion to Extend Deadlines.

### III. 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).

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<sup>3</sup> Included in the OSC was a denial of CTPs July 17, 2017, Motion to Extend Deadlines.

#### IV. LAW

21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)(1), 1140.14(a) and 1140.14(b)(1).<sup>4</sup>

#### V. ISSUE

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

#### VI. DEFAULT

I find Respondent was served and is subject to the jurisdiction of this forum, as established by the Certification of Filing filed by CTP. My Order to Show Cause (OSC) is incorporated herein by reference.

My OSC instructed Respondent to Show Cause on or before close of business on July 28, 2017, why Judgment of Default (DJ) should not be entered in favor of the Complainant pursuant to 21 C.F.R. § 17.11.

Respondent failed to file a responsive pleading to my July 21, 2017, OSC.

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 by the July 28, 2017, deadline, has waived its right to a hearing.

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<sup>4</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

## VII. ALLEGATIONS

### A. Agency's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Parks Place / Shell Food Mart, located at 608 West Yelm Avenue, Yelm, Washington 98597. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

During an inspection of Parks Place / Shell Food Mart conducted on November 17, 2016, an FDA-commissioned inspector documented the following violation:

- 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 cigarettes on November 17, 2016, at approximately 4:17 PM.

### B. Respondent's recitation of facts

"I am sanding (sic) evidence, copy from my system cashier (sic) transactions log with 2 receipts that regard to transactions. Transaction between 16:13 PM 11/17/16 and 16:22 PM 11/17/16, there is no other transactions. Our systems have ID verifier. Any customer buys a tobacco product we check ID and without verified, transactions cannot go through. Receipt at 16:22PM 11/17/16, someone bought American sprite menthol. As you can see receipt shows 'customer ID verified 11/14/78' printout birthdates. I am disputing my penalty."

## VIII. SANCTIONS (STRIKING RESPONDENT'S ANSWER)

Due to noncompliance with my July 21, 2017, OSC, I am striking Respondent's answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. 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.

For purposes of this decision, I assume the facts alleged in the Complaint are true and conclude the default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with my orders. 21 C.F.R. § 17.11.

Therefore, under FDA's current policy, the violations described in the Complaint counts as three (3) violations for purposes of computing the civil money penalty in the instant case. See *Guidance for Industry*, at 13-15.

I find and conclude Respondent committed three (3) violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), 21 C.F.R. § 1140.14(a) and 21 C.F.R.

§ 1140.14(b)(1) within a 24-month period as set forth in the Complaint and grant<sup>5</sup> CTPs July 31, 2017, Motion for Default Judgment.

## IX. PRIOR VIOLATIONS

On August 19, 2015, CTP initiated a previous civil money penalty action, CRD Docket Number C-15-3585, FDA Docket Number FDA-2015-H-2782, against Respondent for three<sup>6</sup> violations of 21 C.F.R. pt. 1140 within a twenty-four month period. The two 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, 608 West Yelm Avenue, Yelm, Washington 98597, on April 25, 2015.

An Initial Decision and Default Judgment, was entered by Administrative Law Judge Catherine Ravinski on April 13, 2016, which found that the “facts establish[ed] Respondent Parks Place / Shell's liability under the Act ...[.]” The previous action concluded when the Initial Decision and Default Judgment became final on Friday, May 13, 2016.

I find and conclude Respondent committed three (3) violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), 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.

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<sup>5</sup> The granting of the Motion for Default Judgment renders it unnecessary to rule on CTPs July 31, 2017, Motion to Extend Deadlines.

<sup>6</sup> On May 29, 2014, CTP issued a Warning Letter to Shell/Food Mart. CTP did not include the violation that was the basis of the Warning Letter when determining the amount of this civil money penalty because it falls outside of the twenty-four month period.

## 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) (2015)*, available at <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf> [hereinafter *Guidance for Industry*], at 13-15. 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 of June 30, 2016.

## 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, by failing to respond, 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 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).<sup>7</sup>

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<sup>7</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 § 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

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)).

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) and 21 C.F.R. § 1140.14(a) in that a person younger than 18 years of age was able to purchase cigarettes on November 17, 2016 and April 25, 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 April 25, 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.

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F.3d 1434 (1998) at 1440.

The conduct set forth above on November 17, 2016 and April 25, 2015 count as three (3) 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

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 three (3) violations in a twenty-four 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 respond to my Order to Show Cause.
- 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 \$550.

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