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

Center for Tobacco Products,
Complainant

v.

Duran Robles Ignacio
d/b/a Leo Grocery,
Respondent

FDA Docket No. FDA-2017-H-3850
CRD Docket No. T-17-4954

Decision No. TB2477

Date: March 1, 2018

SUMMARY DECISION

Found:

1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)(1) and (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), (a)(2)(i), and (a)(4) as charged in the prior complaint; and
3) Respondent committed six (6) 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[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	Duran Robles Ignacio d/b/a Leo Grocery
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 July 5, 2017 alleging that FDA documented six (6) violations within a 48-month period.

Duran Robles Ignacio d/b/a Leo Grocery (Respondent or Leo Grocery) filed an Answer, dated July 14, 2017. In its Answer, Respondent admitted the violations alleged in the current complaint and agreed that the $11,182 CMP sought by CTP was appropriate. On July 27, 2017, Judge Bill Thomas, the Administrative Law Judge previously presiding over this matter, issued an order directing the parties to discuss settling the case. Judge Thomas also informed the parties that if a settlement was not reached, benchmarks would be established to move this case forward. On September 25,

[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).

2017, the parties filed a Status Report advising that they were unable to reach a settlement.

On October 5, 2017, Judge Thomas issued an Acknowledgment and Pre-Hearing Order (APHO) in which he set a schedule for pre-hearing exchanges of evidence and argument. On November 6, 2017, CTP filed a Motion for Summary Decision requesting that Judge Thomas "enter summary decision for CTP." Subsequently on December 22, 2017, CTP timely filed its pre-hearing exchange which contained an informal brief and 14 proposed exhibits, including the written direct testimony of two proposed witnesses.

On December 20, 2017, this case was transferred to me. On December 29, 2017, I issued an Order Granting Motion for Summary Decision and Order to Show Cause to Respondent (OSC). Respondent was ordered to show cause on or before January 5, 2018 why Summary Decision should not be entered in favor of CTP. Respondent failed to file any responsive pleadings to my OSC.

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).

IV. LAW

21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)(1), (a)(2)(i), and (a)(4).

V. ISSUE

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)(1), (a)(2)(i), and (a)(4) as alleged in the complaint?

VI. SUMMARY DECISION

Pursuant to 21 C.F.R. § 17.17(b), I am authorized to grant a motion for summary decision "if the pleadings, affidavits, and other materials filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law."

I find that Respondent was served which Respondent has admitted, and that Respondent is subject to the jurisdiction of this forum, as established by its July 14, 2017 Answer.

In its Answer, Respondent conceded that the violations for which CTP seeks a money penalty occurred as alleged in the complaint, and that the penalty is appropriate.

Further, in my December 29, 2017 OSC, I ordered Respondent to Show Cause on or before close of business on January 5, 2018, why Summary Decision should not be entered in favor of the Complainant pursuant to 21 C.F.R. § 17.17.

Respondent failed to file responsive pleadings to CTP's Motion for Summary Decision and my OSC. Thus, pursuant to 21 C.F.R. §§ 17.17, I find it appropriate to grant CTP's Motion for Summary Decision and find Respondent liable under the Act.

VII. ALLEGATIONS

A. Agency's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Leo Grocery, located at 71 Washington Street, Waterbury, Connecticut 06706. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

During an inspection of Leo Grocery conducted on May 18, 2017, 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 100s cigarettes on May 18, 2017, at approximately 9:13 AM; 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 May 18, 2017, at approximately 9:13 AM.

B. Respondent's recitation of facts

Respondent admitted the violations as alleged in the complaint.

VIII. PRIOR VIOLATIONS

On January 11, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-423, FDA Docket Number FDA-2015-H-4851, against Respondent for four (4)[3] 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, 71 Washington Street, Waterbury, Connecticut 06706, on April 13, 2015 and September 18, 2015.

[3] Two violations were documented on April 13, 2015 and three violations were documented on September 18, 2015. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

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

I find and conclude Respondent committed six (6) violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), 21 C.F.R. § 1140.14(a)(2)(i), and 21 C.F.R. § 1140.14(a)(4) within a 48-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)). As set forth above, Respondent admitted the violations occurred as alleged in the complaint and also conceded that the civil money penalty sought by CTP is appropriate.

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 admission I find all the allegations in the complaint to be true.

I find and conclude that 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 tobacco products on April 13, 2015, September 18, 2015, and May 18, 2017.

I also find and conclude that Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i) on April 13, 2015, September 18, 2015, and May 18, 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 tobacco product purchasers are younger than 18 years of age.

Further, I find and conclude that Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(4) on September 18, 2015, in that Respondent violated the prohibition against breaking or otherwise opening any cigarette package to sell or distribute individual cigarettes.

The conduct set forth above on April 13, 2015, September 18, 2015, and May 18, 2017 counts as six (6) 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 also,* 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

Respondent agreed that the civil money penalty sought by CTP is appropriate. Therefore, no mitigation is considered.

XIV. CONCLUSION

Respondent committed six (6) violations in a 48-month period and thus, 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 admitted the violations occurred as alleged in the Complaint.
b. I find Respondent failed to respond to my Order to Show Cause.
c. I find the facts alleged in the complaint to be true.
d. I find the facts set forth in the complaint establish liability under the relevant statute.
e. I assess a monetary penalty in the amount of $11,182.

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