

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-5286)

Complainant,

v.

Fakin Jacks LLC  
d/b/a Holy Smoke,

Respondent.

Docket No. T-17-6189

Decision No. TB2476

Date: March 1, 2018

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Fakin Jacks LLC d/b/a Holy Smoke, that alleges that Holy Smoke impermissibly sold cigarettes or smokeless tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent Holy Smoke was previously found liable for four violations of regulations found at 21 C.F.R. PT. 1140 and, therefore, CTP seeks to impose an \$11,182 civil money penalty against Respondent Holy Smoke. Respondent filed an Answer to the Complaint, but has failed to comply with multiple judicial directions and orders during the hearing process. I therefore strike Respondent's answer and issue this decision of default judgment.

## **I. Procedural History**

On August 31, 2017, CTP began this matter by serving a Complaint on Respondent Holy Smoke, seeking an \$11,182 civil money penalty. On October 1, 2017, Respondent timely filed its answer to CTP's Complaint in the DAB E-File system. On October 17, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO). The APHO generally explained to the parties what they must do to present evidence and arguments in this case. Specifically, it explained that the parties may request copies of documents relevant to this case and that the requesting party must serve the request for documents no later than November 20, 2017. As indicated in the APHO, a party who received such a request was required to provide the requested documents no later than 30 days after the request had been made. CTP served a Request for Production of Documents (RFP) on Respondent on October 20, 2017.

On November 28, 2017, pursuant to 21 C.F.R. § 17.23(a), CTP filed a Motion to Compel Discovery indicating that CTP had not received a response to its request for production of documents. On November 28, 2017, CTP also filed a Motion to Extend Deadlines. A December 4, 2017 letter issued by my direction allowed Respondent until December 18, 2017 to file a response to CTP's motion to compel discovery. On December 4, 2017, I also issued an Order that extended the parties' pre-hearing exchange deadlines.

On December 22, 2017, I issued an Order that granted CTP's motion to compel discovery. I noted that Respondent had not filed a response to CTP's motion to compel discovery. In that Order, I ordered Respondent to comply with CTP's RFP by January 22, 2018. I warned that "[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." The December 22, 2017 Order also extended the parties' pre-hearing exchange deadlines.

On January 23, 2018, CTP filed a Status Report and Motion to Impose Sanctions advising me that Respondent had not complied with my December 22, 2017 Order and asking me to strike the Respondent's answer and issue a default judgment in this case. On January 23, 2018, CTP also filed a second motion to extend the pre-hearing exchange deadlines. In a January 25, 2018 letter issued by my direction, Respondent was given until February 7, 2018 to file a response to CTP's motion.<sup>1</sup> The January 25, 2018 letter also extended the parties' pre-hearing exchange deadlines. To date, Respondent has not filed a response to CTP's Motion to Impose Sanctions.

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<sup>1</sup> A February 5, 2018 letter further allowed Respondent until February 9, 2018 to respond to CTP's motion.

## II. Striking Respondent's Answer

Pursuant to 21 C.F.R. § 17.35, I am granting CTP's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with multiple judicial orders and directions. Specifically, Respondent has not complied with: (1) the deadline set forth in the Acknowledgment and Pre-Hearing Order for responding to any discovery request and (2) the order granting CTP's motion to compel discovery issued on December 22, 2017. Additionally, Respondent did not respond to the letter issued by my direction on February 5, 2018 soliciting a response to CTP's motion to impose sanctions. 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 here that Respondent's repeated failure to comply with my orders and directions is sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

## III. Default Decision

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 the orders. 21 C.F.R. § 17.11. Specifically:

- On November 17, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-416, FDA Docket Number FDA-2015-H-4751 (*see also*, CRD Docket Number C-15-933, FDA Docket Number FDA-2015-H-0127), against Respondent for four violations of 21 C.F.R. pt. 1140. CTP alleged those violations to have occurred at Respondent's business establishment, 1556 East Olive Way, Seattle, Washington 98102, on May 2, 2014, August 21, 2014, and September 2, 2015. Complaint ¶ 9.
- 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." Complaint ¶ 10.
- At approximately 12:19 PM on May 30, 2017, at Respondent's business establishment, 1556 East Olive Way, Seattle, Washington 98102, an FDA-commissioned inspector documented Respondent's staff selling a package of Camel Blue 99's cigarettes to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic

identification containing a date of birth, that the purchaser was 18 years of age or older. Complaint ¶ 7.

These facts establish Respondent Holy Smoke's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1)<sup>2</sup>, no retailer may sell cigarettes and/or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette and/or smokeless tobacco purchasers are younger than 18 years of age.

Under 21 C.F.R. § 17.2, an \$11,182 civil money penalty is permissible for six violations of the regulations found at 21 C.F.R. pt. 1140.

### **ORDER**

For these reasons, I enter default judgment in the amount of \$11,182 against Respondent Fakin Jacks LLC d/b/a Holy Smoke. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

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/s/  
Wallace Hubbard  
Administrative Law Judge

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<sup>2</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.