

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Azaan Petro Inc.  
d/b/a Crown,

Respondent.

Docket No. T-16-848  
FDA No. FDA-2016-H-1508

Decision No. TB586

Date: December 8, 2016

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) initiated a \$500 civil money penalty (CMP) action against Respondent for unlawfully selling cigarettes to minors, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, in violation of 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. During the hearing process, Respondent failed to comply with a judicial direction. I therefore strike Respondent's answer and issue this decision of default judgment.

**I. Procedural History**

CTP served its complaint on Respondent on June 23, 2016. Respondent answered the complaint, and I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for parties' submissions, including the September 2, 2016 deadline to request that the opposing party provide copies of documents relevant to this case. Additionally,

the APHO stated that a party receiving such a request must provide the requested documents no later than 30 days after the request.

CTP served Respondent with its Request for Documents on September 2, 2016. On October 12, 2016, CTP filed a Motion to Compel Discovery indicating that CTP had not received a response to its request for production of documents. *See* 21 C.F.R. § 17.23(a). On October 13, 2016, a letter was issued by my direction that gave Respondent until October 27, 2016 to file a response to CTP's Motion to Compel Discovery.

On November 1, 2016, I issued an Order that granted CTP's Motion to Compel Discovery. In that Order, I stated that Respondent shall comply with CTP's Request for Production of Documents by November 10, 2016. On November 18, 2016, CTP filed a Status Report and Motion to Impose Sanctions, stating that "[a]s of the date of this filing, Respondent has neither produced any of the requested documents, nor contacted Complainant or Counsel for Complainant regarding the matter."

## **II. Striking Respondent's Answer**

Due to noncompliance with my order granting CTP's Motion to Compel Discovery, 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(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).

## **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 that default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with my order. 21 C.F.R. § 17.11. Specifically:

- Respondent owns Crown, an establishment that sells tobacco products and is located at 5101 York Road, Baltimore, Maryland 21212. Complaint ¶¶ 6-7.
- During an inspection of Respondent's establishment on February 25, 2015, at approximately 2:55 PM, an FDA-commissioned inspector documented that "a

person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]” The inspector also documented that “the minor’s identification was not verified before the sale . . . .” Complaint ¶ 10.

- On April 16, 2015, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from February 25, 2015. The letter explained that the observations constituted violations of regulations, and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on December 9, 2015, at approximately 2:42 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]” The inspector also documented that “the minor’s identification was not verified before the sale . . . .” Complaint ¶ 8.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 906(d) of the Act. 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). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1)<sup>1</sup>. The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on February 25, 2015, and December 9, 2015. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

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<sup>1</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

