

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Innovations Inc. d/b/a The Tobacco Discount Store,

Respondent.

Docket No. C-14-162
FDA Docket No. FDA-2013-H-1383

Decision No. CR3079

Date: January 13, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated the above-captioned matter when it filed an Administrative Complaint for Civil Money Penalties (Complaint) with the Departmental Appeals Board, Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. CTP previously initiated a civil money penalty action, CRD Docket Number C-13-243, FDA-2013-H-0017, against the Respondent, which ended when Respondent admitted the previous violations and CRD closed the case.¹ CTP now seeks to impose additional civil money penalties under the Federal Food, Drug, and Cosmetic Act (Act) and the Act's implementing regulations.

¹ CTP initiated the previous action by filing an Administrative Complaint for Civil Money Penalties with CRD dated January 2, 2013 (January 2, 2013 Complaint). CTP attached the January 2, 2013 Complaint to the Complaint it filed when it initiated the present matter.

The Complaint alleges the following facts. Respondent owns an establishment that sells tobacco products and is located at 1312 South Baltimore Street, Kirksville, Missouri 63501. Complaint ¶ 3. CTP conducted three inspections of the establishment. Complaint ¶ 9.

In the civil money penalty action that CTP initiated on January 3, 2013, CTP alleged that Respondent had committed four violations of regulations found at 21 C.F.R. Part 1140. Complaint ¶ 10. These violations occurred on October 7, 2011, and April 22, 2012. January 2, 2013 Complaint ¶¶ 1, 10. Omar Faruq settled the claims against Respondent when:

[He] admitt[ed] that the violations described in the Complaint filed in FDA Docket Number FDA-2013-H-0017, CRD Docket Number C-13-243 occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions.

Complaint ¶ 11. As a result, CRD closed the case on February 14, 2013. Complaint ¶ 11.

During a subsequent inspection of Respondent's establishment, FDA-commissioned inspectors documented the following:

[A] person younger than 18 years of age was able to purchase a package of L & M cigarettes on April 22, 2013, at approximately 9:36 AM; and . . . the minor's identification was not verified before the sale, as detailed above, on April 22, 2013, at approximately 9:36 AM.

Complaint ¶ 1.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on November 14, 2013, via United Parcel Service. Respondent previously admitted that it had committed four violations of 21 C.F.R. Part 1140. Complaint ¶¶ 10-11. CTP charged Respondent with new violations of 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor) and 21 C.F.R. § 1140.14(b)(1) (failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth). Complaint ¶ 1. CTP asked the CRD to impose a \$10,000 civil money penalty based on six alleged violations of the regulations in a 48-month period. Complaint ¶ 13.

The Complaint provided detailed instructions related to filing an answer and requesting an extension of time to file an answer. Complaint ¶¶ 14-18, 20-22. The Complaint stated that failure to file an answer could result in the imposition of a civil money penalty against Respondent. Complaint ¶ 19. Further, after CTP filed the Complaint, CRD sent Respondent an Initial Order informing Respondent of the requirement to file an answer to avoid a default judgment. CRD sent a form answer along with the Initial Order that Respondent could fill out and file with CRD. Respondent neither filed an answer nor requested an extension of time within the 30-day time period prescribed in 21 C.F.R. § 17.9.

If a respondent does not file an answer within 30 days of a properly served complaint, the regulations provide that:

[T]he presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:

- (1) The maximum amount of penalties provided for by law for the violations alleged; or
- (2) The amount asked for in the complaint, whichever amount is smaller.

21 C.F.R. § 17.11(a). Further, a failure to file a timely answer means that “the respondent waives any right to a hearing and to contest the amount of the penalties and assessments” imposed in the initial decision. 21 C.F.R. § 17.11(b).

Accepting the facts alleged in the Complaint as true, I find that those facts establish Respondent’s liability under the Act. *See* 21 U.S.C. §§ 333(f)(9), 387c(a)(7)(B), 387f(d); 21 C.F.R. §§ 1140.1(b), 1140.14. I also find that CTP’s request to impose a \$10,000 civil money penalty is permissible. *See* 21 C.F.R. § 17.2.

Therefore, Respondent is directed to pay a civil money penalty in the amount of \$10,000. This initial decision becomes final and binding upon both parties 30 days after the date of its issuance. 21 C.F.R. § 17.11(b).

It is so ordered.

/s/
Scott Anderson
Administrative Law Judge