

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Vicente Cruz
d/b/a ENR Market,

Respondent.

Docket No. C-14-870
FDA Docket No. FDA-2014-H-0378

Decision No. CR3249

Date: May 30, 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-13-1017, FDA-2013-H-0844,¹ against Respondent, which ended when Respondent admitted the previous violations and

¹ CTP filed an Administrative Complaint for Civil Money Penalties with the CRD dated August 9, 2013 (August 9, 2013 Complaint). CTP attached the August 9, 2013 Complaint to the Complaint it filed when it initiated the present matter.

CRD closed the case.² CTP seeks to impose civil money penalties under the Federal Food, Drug, and Cosmetic Act (Act) and the Act's implementing regulations.

The Complaint alleges the following facts. Respondent owns an establishment that sells tobacco products and is located at 431 Zion Street, Hartford, Connecticut 06106. Complaint ¶ 3. CTP documented violations while conducting three inspections of the establishment. Complaint ¶ 9.

In the civil money penalty action that CTP initiated on August 9, 2013, CTP alleged that Respondent committed three violations of regulations found at 21 C.F.R. pt. 1140. Complaint ¶ 10. These violations occurred on August 7, 2012, and January 29, 2013. Complaint ¶ 10. Vicente Cruz settled the claims against Respondent when:

[He] admitt[ed] that the violations described in the Complaint filed in FDA Docket Number FDA-2013-H-0844, CRD Docket Number C-13-1017 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 September 19, 2013. Complaint ¶ 11.

During a subsequent inspection of Respondent's establishment, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on October 21, 2013, at approximately 9:52 AM[.] The inspectors also documented that Respondent was "selling individual cigarettes" Complaint ¶ 1.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on April 4, 2014, via United Parcel Service. Respondent previously admitted that it had committed three violations of 21 C.F.R. pt. 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(d) (breaking or otherwise opening a cigarette package to sell or distribute individual cigarettes). Complaint ¶ 1. CTP asked

² Although the August 9, 2013 Complaint shows Respondent as "Vicente Cruz d/b/a ENR Grocery or EnR Market" instead of "Vincente Cruz d/b/a ENR Market," I note that Respondent is Mr. Cruz regardless of the name under which he is doing business.

The CRD to impose a \$5,000 civil money penalty based on five alleged violations of the regulations in a 36-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 \$5,000 civil money penalty is permissible. *See* 21 C.F.R. § 17.2.

