

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Pamela Antonetty d/b/a Bodega 24,

Respondent.

Docket No. C-12-946
FDA Docket No. FDA-2012-H-0704

Decision No. CR2604

Date: August 31, 2012

INITIAL DECISION AND DEFAULT JUDGMENT

I enter a default judgment against Respondent, Pamela Antonetty d/b/a Bodega 24. The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent that alleges facts and legal authority that are sufficient to justify the imposition of a civil money penalty of \$2,000. Respondent did not timely answer the complaint nor did she request an extension of time within which to file an answer.

CTP began this case by serving a complaint on Respondent and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Respondent impermissibly sold tobacco products to a minor, violating the Federal Food,

Drug, and Cosmetic Act (Act) and its implementing regulations at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$2,000.

On July 13, 2012, CTP served the complaint on Respondent by United Parcel Service, as is provided for by 21 C.F.R. §§ 17.5 and 17.7. In the complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time in which to file answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty. Respondent did not file an answer within the time provided by regulation.

I am required to issue a default judgment if the complaint is sufficient to justify a penalty and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the administrative complaint and Respondent's failure to answer them.

For purposes of this decision, I assume that the following facts alleged in the complaint are true. Specifically:

- Respondent owns an establishment that sells tobacco products and which does business as Bodega 24. The business is located at 154 High Street, Holyoke, MA 01040.
- On April 27, 2011, an FDA-commissioned inspector made observations at Respondent's place of business consisting of: sale of cigarettes or smokeless tobacco to a minor under the age of 18; and failure to identify the age of an individual through photographic identification.
- On July 14, 2011, CTP issued a Warning Letter to Respondent that recited the April 27, 2011, observations. The letter informed Respondent that the observed facts constituted violations of regulations at 21 C.F.R. §§ 1140.14(a) and 1140.14(b) that prohibited sales of tobacco products to individuals under the age of 18 and that required verification of age of purchasers of tobacco products. It advised Respondent that failure to correct the violations could result

