

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2014-H-1363)

Complainant,

v.

Chungu Wembi  
d/b/a Wembi-6 Grocery,

Respondent.

Docket No. C-14-1874

Decision No. CR3463

Date: November 14, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Chungu Wembi d/b/a Wembi-6 Grocery, at 269 South Hoskins Road, Charlotte, North Carolina 28208, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Wembi-6 Grocery impermissibly made individual cigarettes available for sale on multiple occasions, 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. CTP seeks to impose a \$250 civil money penalty against Respondent Wembi-6 Grocery.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 17, 2014, CTP served the complaint on Respondent Wembi-6 Grocery by United Parcel Service. 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 an 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 Wembi-6 Grocery has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- At an undisclosed time on August 3, 2013, at Respondent's business establishment, 269 South Hoskins Road, Charlotte, North Carolina 28208, an FDA-commissioned inspector observed the presence of individual unpackaged cigarettes. Specifically, Respondent's staff confirmed the cigarettes were available for individual purchase for \$0.35;
- In a warning letter issued on October 3, 2013, CTP informed Respondent of the inspector's August 3, 2013 observation, and that such an action violates federal law, 21 C.F.R. § 1140.14(d). The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action;
- At an undisclosed time on March 12, 2014, at Respondent's business establishment, 269 South Hoskins Road, Charlotte, North Carolina 28208, FDA-commissioned inspectors documented the presence of individual unpackaged cigarettes for sale. Specifically, Respondent's staff indicated the cigarettes were on sale for \$0.35.

These facts establish Respondent Wembi-6 Grocery'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 § 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 § 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). Under 21 C.F.R. § 1140.14(d) no retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes.

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

