Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

Sawa Tobacco, Inc. d/b/a Orlando Cigar and Tobacco Shop Docket No. A-17-108 Decision No. 2813 August 24, 2017

DECISION TO DECLINE REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

This case is before the Departmental Appeals Board (DAB) on a notice filed by Sawa Tobacco, Inc. d/b/a Orlando Cigar and Tobacco Shop (Respondent) seeking to appeal a July 17, 2017 Administrative Law Judge (ALJ) initial decision, *Sawa Tobacco, Inc. d/b/a Orlando Cigar and Tobacco Shop*, DAB TB1650 (2017). In that decision, the ALJ entered default judgment in the amount of \$550 against Respondent for violating the regulations prohibiting the sale of tobacco products to minors and requiring verification of the purchaser's age through photo identification three times within 24 months, after Respondent did not respond to two orders by the ALJ directing Respondent to answer the Food and Drug Administration's (FDA's) requests for documents.

We decline review because Respondent did not file, within the 30-day time period for appealing an ALJ decision, a notice of appeal as required by the regulations governing these appeals. The regulations require that a notice of appeal "must identify specific exceptions to the initial decision [i.e., the ALJ decision], must support each exception with citations to the record, and must explain the basis for each exception." 21 C.F.R. § 17.47(c); *see also* 21 C.F.R. § 17.47(b)(2) (notice of appeal must be filed within 30 days; Board may extend that period if an extension is requested *within the initial 30-day period for filing the notice of appeal*).

Instead of a notice of appeal that complies with the regulations, Respondent filed a copy of its answer to the FDA's complaint that began the case before the ALJ. Respondent's answer was prepared before the ALJ issued the decision and thus does not allege any error in the ALJ Decision.

We note that Respondent's representative, after filing the copy of Respondent's answer to the FDA complaint, communicated with the Appellate Division Director by email and telephone, seeking guidance about how to appeal the ALJ Decision.

Respondent was directed to the Appellate Division Guidelines for this type of case, which were provided to Respondent with the ALJ Decision. Those Guidelines explain what must be included in a notice of appeal of an ALJ decision. Yet, Respondent still failed to file, within the 30-day period in the regulations, either a notice of appeal that satisfies the regulations or a request for an extension of time to file such a notice of appeal.

Respondent has thus not identified any basis to disturb the ALJ's factual findings or legal conclusions on any issue, and the time for filing a notice of appeal, or for requesting an extension to file a notice of appeal, has expired. We therefore decline review of the ALJ's initial decision. Thus, the ALJ's initial decision becomes final and binding 30 days after this declination. *See* 21 C.F.R. §17.47(j).

/s/ nce B. Tobias

Constance B. Tobias

/s/

Susan S. Yim

/s/

Christopher S. Randolph Presiding Board Member