Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

Xpress Fuel Mart, Inc. d/b/a Fast Trac / BP Docket No. A-19-6 Decision No. 2907 October 31, 2018

DECISION TO DECLINE REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

This case is before the Departmental Appeals Board (DAB) on a notice of appeal filed by Xpress Fuel Mart, Inc. d/b/a Fast Trac / BP (Respondent) seeking to appeal an Initial Decision and Default Judgment, *Xpress Fuel Mart, Inc. d/b/a Fast Trac / BP*, DAB TB3139 (2018), issued by an Administrative Law Judge (ALJ) on September 27, 2018. In that initial decision, the ALJ entered default judgment against Respondent for failing to file an answer to the Complaint brought by the Center for Tobacco Products (CTP) of the United States Food and Drug Administration (FDA), and affirmed a \$5,591 civil money penalty sought by CTP for five violations of the regulations found at 21 C.F.R. Part 1140 within a 36-month period. On October 11, 2018, the ALJ issued an order (Order) denying Respondent's motion to reopen the initial decision because Respondent failed to meet its burden under 21 C.F.R. § 17.11(d) to demonstrate that extraordinary circumstances prevented it from filing an answer in a timely manner.¹

¹ In the Order, the ALJ stated that the DAB's Civil Remedies Division (CRD) issued Guidance Establishing Procedures (GEP) on September 8, 2018 instructing Respondent that it must file its answer within 30 days of service of the Complaint. Order at 2. The record shows that the GEP was actually issued by the CRD on August 7, 2018, not September 8, 2018 as indicated by the ALJ. *See* CRD Docket Entry 2.

We considered Respondent's notice of appeal and examined the record. Based on this review, we find no basis to disturb the ALJ's factual findings or legal conclusions on any issue. We therefore decline review of the ALJ's initial decision. *See* 21 C.F.R. § 17.47(j). Thus, the ALJ's initial decision constitutes the final decision of the FDA and becomes final and binding 30 days after this declination. *Id*.

	/s/
Constance B. Tobias	
	/s/
Susan S. Yim	
	/s/
Sheila Ann Hegy	
Presiding Board Member	