

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Dina Monster, Inc., d/b/a D.C.'s Downtown
Docket No. A-17-43
Decision No. 2810
August 10, 2017

**DETERMINATION TO DECLINE REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

This case is before us on a notice of appeal filed by Dina Monster, Inc., d/b/a D.C.'s Downtown (Respondent), from an Order issued by an Administrative Law Judge (ALJ), *Dina Monster, Inc., d/b/a D.C.'s Downtown, Order Denying Motion to Reopen*, Civil Remedies Docket No. T-16-1528 (Jan. 12, 2017), Decision No. TB425. The ALJ's Order denied Respondent's motion to reopen Decision No. TB425 (Nov. 4, 2016), the ALJ's Initial Decision and default judgment assessing a civil money penalty (CMP) in the amount of \$11,002 against Respondent for violating the Federal Food, Drug, and Cosmetic Act. The ALJ issued the initial decision pursuant to 21 C.F.R. § 17.11 after Respondent failed to file a timely answer to the Food and Drug Administration's complaint seeking to impose the CMP. Respondent requested reopening pursuant to 21 C.F.R. § 17.11(d), which permits the ALJ, upon a showing that "extraordinary circumstances" prevented a respondent from filing a timely answer, to withdraw an initial decision and permit the respondent to answer the complaint. In his Order, the ALJ concluded that the assertions in Respondent's motion did not constitute extraordinary circumstances.

A respondent may appeal an ALJ's "initial decision, including a decision not to withdraw a default judgment," to the "Departmental Appeals Board (DAB)," which consists of Board Members supported by the Appellate Division. 21 C.F.R. § 17.47(a). The DAB may "decline to review the case, affirm the initial decision," or "reverse the initial decision . . . , or increase, reduce, reverse, or remand any civil money penalty determined" by the ALJ. 21 C.F.R. § 17.47(j).

After reviewing the record, we have determined that we need not render a separate decision.¹ We therefore decline review of and summarily affirm the ALJ's initial decision. Thus, that decision becomes final and binding on the parties "30 days after the declination." 21 C.F.R. §17.47(j).

_____/s/
Sheila Ann Hegy

_____/s/
Constance B. Tobias

_____/s/
Christopher S. Randolph
Presiding Board Member

¹ We note that Petitioner submitted new evidence with its request for Board review, but the Board will not remand for consideration of this new evidence because Petitioner failed to demonstrate that there were reasonable grounds for its failure to adduce this evidence at the ALJ level. *See* 21 C.F.R. § 17.47(i).