

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

Kwik Gas Inc. d/b/a Delta
Docket No. A-18-13
Decision No. 2852
February 20, 2018

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

Respondent Kwik Gas Inc. d/b/a Delta (Delta) appeals an Administrative Law Judge's (ALJ's) "Initial Decision and Default Judgment" imposing a \$5,591 civil money penalty (CMP) against Delta for committing five violations of the federal tobacco sales regulations – selling cigarettes to minors and failing to verify the purchaser's age via photographic identification – within a 36-month period. *Kwik Gas Inc. d/b/a Delta*, DAB TB2096 (2017) (ALJ Decision). The ALJ entered the default judgment after Respondent failed to respond to an administrative complaint that the Center for Tobacco Products (CTP) of the U.S. Food and Drug Administration (FDA) issued seeking to impose the CMP. For the reasons explained below, we affirm the ALJ Decision imposing the CMP.

Legal Background

The FDA has issued regulations under the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, that "establish restrictions on the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products" and hold each retailer of tobacco products "responsible for ensuring that the cigarettes, smokeless tobacco, or covered tobacco products" it sells or holds for sale "comply with all applicable requirements" in Part 1140. 21 C.F.R. §§ 1140.2, 1140.10. Among those requirements are that "[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age" and that, in face-to-face sales, "each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age" unless the purchaser is over the age of 26. 21 C.F.R. § 1140.14(a)(1), (2).

The Act authorizes FDA to impose CMPs against any person who violates a requirement of the Act that relates to tobacco products. 21 U.S.C. § 333(f)(9). The regulations set out a table of annually-adjusted CMP amounts that may be imposed for violations of the regulatory requirements, with CMPs increasing for successive violations within a given time period. 21 C.F.R. § 17.2, adopting 45 C.F.R. § 102.3 (table). In 2017, the maximum CMP “in the case of a fifth tobacco product regulation violation within a 36-month period” was \$5,591. 45 C.F.R. § 102.3 (table).

CTP initiates a case by serving a complaint on the retailer and filing it with the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB). 21 C.F.R. §§ 17.3, 17.5, 17.7. Service may be by personal delivery or, as here, by “[c]ertified or registered mail or similar mail delivery service with a return receipt record reflecting receipt[.]” *Id.* § 17.7(a). A retailer may request a hearing to appeal a CMP by filing an answer to the complaint with CRD within 30 days (and may within that time request one 30-day extension). *Id.* § 17.9(a), (c).

If the respondent does not file an answer within the prescribed 30-day time period, the ALJ “shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute . . . shall issue an initial decision within 30 days of the time the answer was due, imposing” either “(1) The maximum amount of penalties provided for by law for the violations alleged; or , . . . (2) The amount asked for in the complaint, whichever amount is smaller.” *Id.* § 17.11(a). A respondent that fails to file a timely answer to a complaint “waives any right to a hearing and to contest the amount of the penalties and assessments imposed,” and “the initial decision shall become final and binding upon the parties 30 days after it is issued.” *Id.* § 17.11(b).

Before an ALJ’s initial decision entering a default judgment for failure to respond to a complaint becomes final, the respondent may file “a motion seeking to reopen on the grounds that extraordinary circumstances prevented the respondent from filing an answer,” in which case “the initial decision shall be stayed pending a decision on the motion.” *Id.* § 17.11(c). If the respondent “can demonstrate extraordinary circumstances excusing the failure to file an answer in a timely manner,” the ALJ “may withdraw the decision . . . and shall grant the respondent an opportunity to answer the complaint as provided in § 17.9(a).” *Id.* § 17.11(d).

A respondent, or CTP, “may appeal an initial decision, including a decision not to withdraw a default judgment,” to the DAB’s Appellate Division (Board). *Id.* § 17.47(a). A notice of appeal “must identify specific exceptions to the initial decision, must support each exception with citations to the record, and must explain the basis for each exception.” *Id.* § 17.47(c). The Board “will consider only those issues raised before the presiding officer [i.e., the ALJ], except that the appellee may make any argument based on the record in support of the initial decision or decision granting summary decision.” *Id.* § 17.47(g).

Background¹

On August 24, 2017, CTP served an administrative complaint (Complaint) on Delta by means of United Parcel Service (UPS). The Complaint sought to impose a CMP of \$5,591 against Delta for violating the regulations governing tobacco sales at least five times in a 36-month period, on March 15, 2015, September 1, 2015, and January 25, 2017. On each occasion, the Complaint alleged, Respondent committed two violations of the Act and its implementing regulations at 21 C.P.R. Part 1140 by (1) selling cigarettes or smokeless tobacco to a person younger than 18 years of age and (2) failing to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

The Complaint specifically alleged that, on January 25, 2017, at approximately 7:56 p.m., an FDA-commissioned inspector documented that staff at Delta sold a package of cigarettes to a person younger than 18 years of age without verifying by photographic identification that the purchaser was 18 years of age or older. The Complaint stated that the violations on March 15 and September 1, 2015 had been the subject of an earlier complaint CTP issued on December 22, 2015 that sought to impose a CMP against Delta for committing three violations of the regulations within a 24-month period.² As a result of the December 2015 complaint, an ALJ entered an order of default and initial decision finding that the two September 1, 2015 violations alleged in the December 2015 complaint had occurred, making no finding as to whether the two violations on March 15, 2015 had occurred, and assessing a CMP of zero dollars and issuing a “judicial Warning letter” against Delta.³

¹ The factual information in this section, unless otherwise indicated, is drawn from the ALJ Decision and the record and is presented to provide a context for the discussion of the issues raised on appeal. We make no new factual findings and omit record citations for undisputed events.

² The earlier complaint sought to hold Delta liable for only one of the two violations committed on March 15, 2015, under an FDA policy to count only one violation from the first inspection that finds one or more violations at an outlet, regardless of the number of violations that were noted.

³ As the Complaint and ALJ Decision note, on June 30, 2016, the Board in another case reversed the ALJ’s method of counting violations that resulted in the zero-dollar CMP against Respondent based on the December 22, 2015 complaint and held that ALJs are not authorized to issue judicial warning letters. *Orton Motor Co., d/b/a Orton’s Bagley*, DAB No. 2717 (2016).

The instant Complaint and CTP's cover letter stated that Delta had to respond to the complaint, that Delta could request a hearing by filing an answer within 30 days after service of the Complaint, that the answer would be deemed to be a request for a hearing unless it stated otherwise, and that failure to file an answer within 30 days after service of the Complaint could result in a default order imposing the proposed CMP of \$5,591. The cover letter also enclosed information on how to respond to the complaint, how to request a hearing, and how to use the DAB's electronic filing system (DAB E-File).

Delta does not deny that it failed to respond to the Complaint. UPS tracking records show that the Complaint was delivered to Delta's business address and signed for on August 24, 2017. Thirty days after August 24, 2017 was September 23, 2017. As of October 20, 2017, the date of the ALJ Decision, Delta had not filed an answer to the Complaint.

The ALJ found that, "[a]s provided for in 21 C.F.R. §§ 17.5 and 17.7, on August 24, 2017, CTP served the complaint on Respondent Delta by United Parcel Service" and that "Respondent Delta has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer." ALJ Decision at 2. Thus, "[p]ursuant to 21 C.F.R. § 17.11," the ALJ "assume[d] that the facts alleged in the complaint (but not its conclusory statements) are true" and "establish Respondent Delta's liability under the Act" for violations of the regulations prohibiting retailers from selling tobacco products to minors and requiring that retailers verify the age of purchasers (under age 26) by photographic identification. *Id.* at 2-3, citing 21 C.F.R. § 1140.14(a)(1), (2). The ALJ further concluded that "[u]nder 21 C.F.R. § 17.2, a \$5,591 civil money penalty is permissible for five violations of the regulations" and "enter[ed] default judgment in the amount of \$5,591 against Respondent[.]" *Id.*

Delta timely appealed the ALJ Decision.

Standard of review

"The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous." 21 C.F.R. § 17.47(k).

Analysis

Delta's notice of appeal does not dispute, or even acknowledge, the ALJ's determination that Delta did not file an answer to the Complaint and thus did not request an ALJ hearing to contest the CMP that CTP sought to impose. ALJ Decision at 2. The notice of appeal instead questions the sufficiency of CTP's evidence that Delta's staff committed

two violations of the tobacco sale regulations on January 25, 2017 by selling cigarettes to a minor without asking for the required identification. Delta states that the “only proof is a pack of cigarette[s] and a picture of a gas station” and its “signage,” which, Delta argues, does not justify the penalty where the FDA inspector did not enter the store and obtain a signed statement from Delta’s employee acknowledging the sale. Notice of Appeal (NA) at 1.

These questions about the sufficiency of the evidence provide no basis to reverse the ALJ Decision. The regulations state that if, as here, a respondent does not answer a complaint, the ALJ “shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute . . . issue an initial decision within 30 days of the time the answer was due” (imposing the smaller of the maximum CMP provided by law or the CMP sought in the complaint). 21 C.F.R. § 17.11(a). That regulation, with which the ALJ complied, meant that Delta’s failure to answer the Complaint resulted in the facts alleged in the Complaint being taken as proven, rendering irrelevant any subsequent challenge to those facts. Thus, the sufficiency of CTP’s evidence of the violations is not at issue before us.

A notice of appeal of an ALJ initial decision “must identify specific exceptions to the initial 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). As Delta’s notice of appeal disputes only the sufficiency of the evidence, an issue not before us, and identifies no other exceptions to the ALJ Decision, it provides no basis to reverse that decision. *See AK, Inc. d/b/a Tesoro*, DAB No. 2815, at 2 (2017) (putative notice of appeal that “does not allege any error in the ALJ Decision . . . has thus not identified any basis to disturb the ALJ’s factual findings or legal conclusions on any issue”).

The Board has declined to review initial decisions by ALJs imposing CMPs for violations of the tobacco sales regulations where the respondent’s “notice of appeal does not identify any [specific] exception to the [ALJ’s initial] [d]ecision.” *Baba Jawala Singh II, Inc. d/b/a 7-Eleven Store 26065A*, DAB No. 2817, at 2 (2017); *E. End Kitchen & Market, LLC*, DAB No. 2798, at 1 (2017). Delta’s failure to file a notice of appeal that identified any exception to the ALJ Decision – other than disputing the facts alleged in the Complaint, which the ALJ correctly took as proven as directed by the regulations – warrants sustaining the ALJ Decision.

Delta, however, filed a reply brief in which, for the first time, it asserts that it did not answer the CTP Complaint because it did not receive it in time to respond. Specifically, Delta asserts it did not file an answer to respond to the allegations in the Complaint because –

We were never made aware of them. . . . Until this docket in question was handed to us and even then it wasn't given to us in a timely manner, but it was delivered to the Dunkin Donuts that is in the same premises as us. As you can understand, this can cause problems because both entities are run [by] different management and have the same address.

Delta Reply (ellipses in original).⁴ The reply goes on to again deny the factual allegations in the Complaint, asserting that Respondent is “NOT guilty of the charges and cannot afford to pay the civil penalties that are placed against [Respondent].” *Id.*

Delta's argument that it did not receive the Complaint in time to respond is not a ground to reverse the ALJ Decision imposing the CMP, where the CMP appeal regulations gave Delta the opportunity to raise that argument before the ALJ in response to the default judgment but Delta failed to do so. The regulations provide that when an ALJ enters a default judgment against a respondent that failed to answer CTP's complaint, the respondent may file “a motion seeking to reopen on the grounds that extraordinary circumstances prevented the respondent from filing an answer,” in which case the ALJ's “initial decision shall be stayed pending a decision on the motion.” 21 C.F.R. § 17.11(c). If the respondent makes that showing, the ALJ may withdraw the decision and permit the respondent to answer the complaint. *Id.* § 17.11(d). A respondent must file a motion to reopen before the ALJ's decision entering the default judgment becomes final, which is “30 days after it is issued.” *Id.* § 17.11(b).

The cover letter transmitting the ALJ Decision to Delta accordingly stated that “[i]f you believe the Default Judgment was entered in error, you may file a motion to reopen with the ALJ within 30 days from the date of the decision.” Delta received the cover letter with the ALJ Decision, which was sent by certified mail to the same address as the Complaint, in time to ask the ALJ to reopen the case, as Delta within that time appealed the ALJ Decision to the Board. *See id.* § 17.47(b)(1) (notice of appeal “may be filed at any time within 30 days after the [ALJ] issues an initial decision”). The appeal

⁴ The “docket in question” that Delta says was received but not in a “timely manner” was presumably the Complaint, as the only documents in the CRD record that were sent to Respondent were the Complaint and the ALJ Decision (each with attached materials), and Respondent timely appealed the ALJ Decision to the Board, indicating that Delta received the ALJ Decision in time to respond. Additionally, the notice of appeal refers to CTP evidence consisting of “a pack of cigarette[s] and a picture of a gas station,” and the materials enclosed with the Complaint included photographs of the pack of cigarettes sold to the minor, and the gas station located at Delta's address. At any rate, if Delta meant something else by its reference to the “docket” it received, it failed to explain that even in its reply on appeal.

regulations state that the Board “will consider only those issues raised before the presiding officer” – i.e., the ALJ. *Id.* § 17.47(g).⁵ Delta here could have raised the issue of its reported untimely receipt of the Complaint before the ALJ (and in its notice of appeal to us), but did not. Had Delta done so, and the ALJ issued a decision rejecting Delta’s arguments about untimely receipt of the Complaint, Delta could have appealed that decision to the Board. *Id.* § 17.47(a) (respondent may appeal “a decision not to withdraw a default judgment”).

Delta also states that it “cannot afford to pay the civil penalties” the ALJ imposed. Delta Reply. We construe this assertion as a request for equitable relief from the ALJ Decision entering default judgment. We, like the ALJ, cannot ignore binding regulations on equitable grounds, and, moreover, we find no unfairness in the ALJ Decision in this case. To the extent the CMP is burdensome, Delta had the ability to challenge it by moving to reopen the ALJ Decision and support its claim that it did not timely receive the Complaint. We see no reason to disturb the ALJ Decision imposing a default judgment as the regulations direct where the Respondent did not take the opportunity the regulations provide to reopen the ALJ proceedings, or to state in the notice of appeal its basis for challenging the ALJ Decision, which was based on Delta’s failure to answer the Complaint. A party facing a possible default judgment or other sanction may not simply fail to follow the process the regulation provides for reopening the default judgment and then belatedly seek relief on appeal.

Delta has not argued that the CMP exceeds the amount authorized by the regulations. The ALJ concluded that “[u]nder 21 C.F.R. § 17.2, a \$5,591 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140.” ALJ Decision at 3. The ALJ did not err. Absent any answer to the Complaint, the regulations called for the ALJ to impose the smaller of “[t]he maximum amount of penalties provided for by law for the violations alleged” or “[t]he amount asked for in the complaint[.]” 21 C.F.R. § 17.11(a). The amount CTP asked for in the complaint, \$5,591, is also the maximum amount the regulations authorize for five violations in 36 months. *Id.* § 17.2; 45 C.F.R. § 102.3 (table).

⁵ The regulations provide an exception not applicable here, by permitting the appellee to “make any argument based on the record in support of the initial decision or decision granting summary decision.” *Id.*

Conclusion

For the reasons explained above, we affirm the ALJ Decision imposing a CMP of \$5,591 against Delta.

/s/
Constance B. Tobias

/s/
Susan S. Yim

/s/
Leslie A. Sussan
Presiding Board Member