Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

Retail LLC d/b/a Super Buy Rite Docket No. A-15-87 Decision No. 2660 October 7, 2015

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Retail LLC d/b/a Super Buy Rite (Super Buy Rite, Respondent) appealed an Administrative Law Judge's (ALJ) decision entering default judgment and sustaining a \$500 civil money penalty (CMP) against Respondent and the ALJ's order denying Respondent's motion to reconsider. Retail LLC d/b/a Super Buy Rite, DAB CR3846 (2015) (ALJ Decision); ALJ Order Denying Motion to Reconsider (June 12, 2015) (Order). The Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) assessed the CMP against Respondent for selling tobacco products to minors and for failing to verify the purchasers' age through means of photo identification, in violation of federal law and regulations. The ALJ struck Respondent's answer to CTP's complaint assessing the CMP and entered default judgment against Respondent as a sanction for Respondent's failures to comply with the ALJ's directions to respond to CTP's request for documents. The ALJ rejected Respondent's claims that it reasonably believed it could delay responding to CTP's request while awaiting a ruling on its untimely motion for a protective order and that the circumstances of the appeal created uncertainty over the deadline for responding. In the Order, the ALJ denied Respondent's motion for reconsideration of the ALJ Decision on the ground that Respondent failed to show that extraordinary circumstances prevented it from complying with CTP's request for documents. For the reasons explained below, we sustain the ALJ Decision and Order.

Applicable Law

The Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, prohibits the "misbranding" of a tobacco product held for sale after shipment in interstate commerce and authorizes CMPs against any person who intentionally violates that prohibition. 21 U.S.C. §§ 331(k), 333(f)(9). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under the Act. 21 U.S.C. § 387c(a)(7)(B). The Act directed the Secretary to establish the CTP within the FDA and authorized the Secretary to issue regulations restricting the sale and distribution of tobacco products. 21 U.S.C. §§ 387a(e), 387f(d).

The regulations, at 21 C.F.R. Part 1140, prohibit the sale of cigarettes or smokeless tobacco "to any person younger than 18 years of age" and require retailers to "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" except that "[n]o such verification is required for any person over the age of 26[.]" 21 C.F.R. § 1140.14(a), (b)(1), (2). The regulations also state that the failure to comply with the applicable provisions of Part 1140 in the sale, distribution, and use of cigarettes and smokeless tobacco "renders the product misbranded" under the Act. 21 C.F.R. § 1140.1(b).

The Act and the regulations governing FDA CMP hearings, at 21 C.F.R. Part 17, specify in dollar amounts the CMPs imposed for violations based on the number of violations and the period of time in which they are committed. The law and regulations set out two parallel CMP schedules, with lower CMPs assessed against a retailer who has an "approved training program." 21 U.S.C. § 333 note; 21 C.F.R. § 17.2. The FDA has stated in CMP guidance documents, however, that it will use the lower schedule for all retailers until it has developed regulations establishing standards for training programs. *Guidance for Industry and FDA Staff – Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* at 13 (May 2015)¹ (FDA Guidance); see also Guidance for *Industry and FDA Staff – Civil Money Penalties for Tobacco Retailers* at 12 (June 2014).² As applicable here, the FDA will assess a CMP of up to \$500 in the case of a third violation within a 24-month period. 21 U.S.C. § 333 note; 21 C.F.R. § 17.2.

The CMP hearing regulations permit a retailer to appeal a CMP by requesting a hearing before a "presiding officer" who is "an administrative law judge qualified under 5 U.S.C. 3105." 21 C.F.R. §§ 17.3(c), 17.9(a). CTP initiates a case before an ALJ by serving a complaint on the retailer (the respondent) 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, 17.33. The respondent must answer the complaint within 30 days or request, within that period, an extension of time to file the answer. 21 C.F.R. § 17.9. Before the ALJ, the parties may request from each other production of documents "that are relevant to the issues before" the ALJ; a party must provide documents within 30 days of receipt of a request for production, and may file a motion for protective order within 10 days of receipt of a request for production. 21 C.F.R. § 17.23(a), (d)(1).

If a respondent does not file a timely answer to CTP's complaint, the ALJ "shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute," the ALJ "shall issue an initial decision within 30 days of the time the

¹ <u>http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf</u> accessed Oct. 6, 2015.

² <u>http://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm339438.pdf</u> accessed Oct. 6, 2015.

answer was due, imposing" the smaller of the maximum CMP provided by law or the amount sought in the complaint. 21 C.F.R. § 17.11(a). The respondent may then, within 30 days, move to reopen the case on the grounds that "extraordinary circumstances" prevented the respondent from filing a timely answer to the complaint. 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; if the ALJ "decides that the respondent's failure to file an answer in a timely manner is not excused, he or she shall affirm the decision" entering default judgment against the respondent. 21 C.F.R. § 17.11(d).

A respondent may appeal the ALJ's decision (which the regulations refer to as the "initial decision") to the "DAB," which consists of Board Members (Board) supported by the Appellate Division. 21 C.F.R. §§ 17.45, 17.47. The Board may "decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion)," or "reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined" by the ALJ. 21 C.F.R. § 17.47(j).

Case Background

As Respondent's arguments hinge on the sequence of the ALJ's and the parties' communications and filings leading up to the ALJ Decision, we recount those events in some detail.³

CTP by complaint filed October 7, 2014 sought a \$500 CMP against Respondent for, on June 10, 2013 and March 23, 2014, selling cigarettes to a person younger than 18 years of age and failing to verify the purchaser's age by means of photographic identification containing the bearer's date of birth, in violation of 21 C.F.R. § 1140.14(a) and (b)(1). Complaint at 1-3. The Complaint alleged that on each date, an FDA-commissioned inspector observed a person younger than 18 years of age purchase a package of cigarettes at Respondent's establishment without Respondent verifying the purchaser's age before the sale.⁴ *Id*. The Complaint stated that after each inspection CTP issued a Notice of Compliance Check Inspection to Respondent's establishment reporting the results of the inspections, and that on July 3, 2013, after the first inspection, CTP sent a Warning Letter to Respondent stating that failure to correct the noncompliance observed June 10, 2013 could result in a CMP action or other regulatory action by FDA. *Id*. at 2-4.

³ The factual information presented in this section is undisputed and is taken from the ALJ Decision and the administrative case record before the ALJ. It is not intended to serve as new findings or substitute for any findings in the ALJ Decision.

⁴ The Complaint and its cover letter from CTP state that the inspection in March 2014 took place on two dates, March 23 and 29, 2014. The Complaint describes events occurring only on March 23, 2014, however.

The Complaint requested a CMP of \$500 against Respondent for three violations of 21 C.F.R. Part 1140 within a 24-month period.⁵ *Id.* at 5. The cover letter from CTP stated that a CD containing supporting documents related to the inspections leading to the CMP was enclosed for Respondent. CTP Ltr. Oct. 6, 2014.

Respondent filed an answer to the Complaint that either denied or disclaimed knowledge of any of the facts alleged in the Complaint (including, for example, denying that Respondent owned an establishment that sold tobacco products and did business under the name Super Buy Rite, located at the address to which CTP sent the Complaint). Answer at 1-3 (unnumbered). Respondent also raised various affirmative defenses, including that the Complaint was barred by CTP's lack of jurisdiction over the subject matter and person, and by the civil law doctrines of res judicata, election of remedies, laches, and unclean hands. *Id.* at 4-5. Respondent also claimed mitigating factors, including that its employees had been educated and informed on several occasions to verify the age of the patron by photographic identification containing the bearer's date of birth. *Id.* at 5.

The ALJ, by pre-hearing order issued December 30, 2014 (PHO), set deadlines for the parties to file a joint status report on the possibility of settlement, to request documents from each other, and to file pre-hearing exchanges consisting of their briefs, witness and exhibit lists, proposed exhibits, and witness statements. The ALJ ordered the parties to serve requests for documents on each other by January 28, 2015, to provide requested documents within 30 days after receiving a request, to file any motion for a protective order within 10 days after receiving a request for documents, and to respond to any motion for a protective order within 10 days of receipt. PHO at 7, citing 21 C.F.R. §§ 17.23(d) (party may file motion for protective order within 10 days of service of a request for production of documents), 17.28 (authorizing ALJ to issue protective orders). The ALJ also ordered the parties to file the joint status report within 30 days, and ordered CTP to file its pre-hearing exchange by March 20, 2015 and Respondent to file its prehearing exchange by April 10, 2015. Id. at 2-3. The ALJ warned the parties that "I may impose sanctions including, but not limited to, dismissal of the complaint or answer, if a party fails to comply with any order (including this order), fails to prosecute or defend its case, or engages in misconduct that interferes with the speedy, orderly, or fair conduct of the hearing." Id. at 8, citing 21 C.F.R. § 17.35.

⁵ The Complaint alleges that Respondent committed two violations during each of the two inspections. The *FDA Guidance* states that "FDA counts 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 and included in a Warning Letter" and that "[f]or any subsequent inspections, FDA may count any or all violations and its general policy is to count all of them individually." *FDA Guidance* at 14. CTP thus assessed a \$500 CMP for three violations within a 24-month period.

The parties served their requests for production of documents on each other on January 28, 2015.

On February 6, 2015, CTP moved for a protective order from Respondent's request for documents, on the ground that the documents Respondent sought were not relevant and that complying with the requests would be unduly burdensome and costly. CTP argued that Respondent primarily sought documents concerning CTP's computer systems including manuals for the hardware and software, and data storage, backup, and archiving; CTP's policies and procedures on training inspectors, minors, agents, and others involved in monitoring the sale of tobacco products; and CTP's organizational charts and documents identifying all employees involved in monitoring sales of tobacco products to minors, with no date limits.

The ALJ on February 12, 2015 gave Respondent 15 days to respond to CTP's motion for a protective order, suspended the March 20, 2015 deadline for CTP to file its prehearing exchange, and told the parties she would set a new deadline once the motion for protective order was resolved. The ALJ also reiterated the deadlines in the PHO and the regulations for responding to a request for documents, 30 days for providing requested documents and 10 days for moving for a protective order. Ltr. Feb. 12, 2015 at 2, citing PHO and 21 C.F.R. § 17.23(a), (d). Respondent filed its response to CTP's motion for a protective order on February 20, 2015.

On February 24, 2015, the ALJ granted CTP's motion and issued a protective order on the ground that the Respondent's request for production was "not reasonably specific and unlikely to lead to the discovery of relevant evidence, thereby making the request unduly burdensome." Protective Order at 1. The ALJ found that "[t]he bulk of the Respondent's request for production seeks documents that would determine how CTP gathers evidence," while "only the evidence itself, and not the manner in which it was generated, is relevant with regard to the outcome of the case." *Id.* The ALJ ordered CTP to file its prehearing exchange by April 8, 2015, and Respondent to file its prehearing exchange by April 25, 2015. *Id.* at 2.

On February 26, 2015, Respondent filed a motion for a protective order from CTP's request for production of documents, which Respondent stated was received January 28, 2015, on the ground that the CTP did "not seek discovery relevant to the two alleged sales of tobacco to minors that are currently the subject" of the Complaint and instead sought "information wholly unrelated to the investigation" of the alleged violations, and that the requests were "overly broad and ambiguous," sought information protected by privilege," and that searching for the documents would "be unduly burdensome" for Respondent. On February 27, 2015, CTP filed an opposition to Respondent's motion for a protective order on the ground that it was filed more than two weeks late and one day before Respondent was required to produce requested documents. Respondent then

asked the ALJ to waive the 10-day time limit for moving for protective order in section 17.23(d)(1) in the interests of justice and fairness and on the ground that it would not prejudice CTP. Each party filed a further reply arguing about the late protective order request.

On March 25, 2015 CTP moved to hold in abeyance the deadlines in ALJ's February 24, 2015 protective order on the ground that CTP would not have sufficient time to file its pre-hearing exchange if the ALJ denied Respondent's motion for a protective order. CTP stated that Respondent consented to the motion.

On April 6, 2015 the ALJ issued two orders. In one order the ALJ denied CTP's motion to hold the deadlines set in the February 24 protective order in abeyance but did again extend the deadlines for the parties' pre-hearing exchanges. In the second order the ALJ denied Respondent's motion for a protective order on the grounds that it was untimely and Respondent, in the motion, had not acknowledged or explained the untimeliness and, in subsequent replies, provided no valid explanation for the untimely motion. The ALJ in the second order also directed Respondent to comply with CTP's request for production and warned that she "may impose penalties on Respondent, including dismissing its hearing request and entering a default judgment in favor of CTP, if Respondent fails to comply." Order Denying R. Motion for Protective Order at 2.

On April 16, 2015, Respondent's counsel phoned the ALJ's staff attorney to determine the deadline for responding to CTP's discovery request. The staff attorney, at the ALJ's direction, responded by letter on April 20, 2015 informing Respondent that the deadline had not been extended from the original deadline of 30 days after Respondent received the discovery request and had been March 2, 2015. Ltr. Apr. 20, 2015. The letter also noted that Respondent had failed to comply with CTP's request for discovery and warned that the ALJ could impose sanctions including striking any part of Respondent's pleadings or other submissions. *Id*.

On April 23, 2015, Respondent's counsel emailed the ALJ's staff attorney stating that Respondent had questions about the discovery deadlines in the April 20 letter. On April 24, CTP moved for sanctions against Respondent for failure to produce documents in response to CTP's request. CTP asked that Respondent's answer to the initial complaint be stricken, default judgment entered against Respondent and the \$500 CMP be awarded or, in the alternative, that Respondent's defenses be stricken and Respondent be precluded from introducing evidence to dispute the violations or in mitigation of the CMPs. CTP stated that it had sought documents related to Respondent's defenses including its denial of the violations, its affirmative defenses, and its claims of mitigating factors. CTP argued that Respondent's ongoing failure to produce any documents was "extremely prejudicial to CTP's ability to prepare its case for hearing, including preparing its pre-hearing exchange and determining whether to move for summary decision." CTP Memo in Support of Motion for Sanctions at 3. Respondent with its opposition to CTP's motion for sanctions, filed April 27, 2015, also included its response to CTP's request for documents. Respondent objected to most of the requests (mostly on the same bases as set out in the belated motion for a protective order that the ALJ had denied) and provided seven documents identified in the ALJ Decision. ALJ Decision at 3.

After further briefing, the ALJ on May 8, 2015 issued her decision striking Respondent's answer and entering default judgment sustaining the CMP.

The ALJ Decision and Order

The ALJ rejected Respondent's contention that "the deadline to produce the requested documents was not clear" and noted that she had never extended that deadline. ALJ Decision at 4. The ALJ found Respondent's repeated failure to comply with CTP's request for documents "sufficiently egregious to warrant striking the answer and issuing a decision." *Id. citing* 21 C.F.R. § 17.35(b) (sanction "shall reasonably relate to the severity and nature of the failure or misconduct"). The ALJ then assumed that the facts CTP alleged in the Complaint were true and concluded that the facts established Respondent's liability under the Act and the imposition of the \$500 CMP. *Id.* at 5-6.

The letter transmitting the ALJ Decision told Respondent it could file with the ALJ a motion to reopen the default judgment on the ground "that extraordinary circumstances prevented you from filing an answer in a timely manner." Ltr. May 8, 2015, *citing* 21 C.F.R. § 17.11. Respondent filed a motion to reconsider that advanced the same arguments Respondent makes on appeal (discussed below). The ALJ denied the motion for reconsideration, holding that "Respondent failed to show that extraordinary circumstances prevented it from complying with discovery requests." Order at 1. The ALJ noted that she had "repeatedly directed Respondent to comply with discovery requests" and "informed Respondent that noncompliance could result in sanctions" including "striking Respondent's answer and issuing a default judgment." *Id.* at 2. She found Respondent's failures to comply with the discovery requests to be more in the nature of negligence rather than extraordinary circumstances.⁶ *Id.*

⁶ The regulations provide for reopening a default judgment, upon a showing of "extraordinary circumstances," when the default judgment was entered because the respondent failed to timely answer the complaint. 21 C.F.R. § 17.11(a) (ALJ shall issue default judgment "[i]f the respondent *does not file an answer* within the time period prescribed" in the regulations), 17.11(b) (respondent "by *failing to file a timely answer* . . . waives any right to a hearing to contest" the CMP), 17.11(d) (respondent seeking to reopen must show "extraordinary circumstances excusing the *failure to file an answer in a timely manner*") (emphasis added). Here, it is not alleged that Respondent failed to timely answer the Complaint, and the ALJ instead entered default judgment after striking Respondent's answer as a sanction for Respondent's failures to comply with the ALJ's directions during the appeal. We accordingly review the ALJ Decision under the standard the Board typically applies to reviewing an ALJ's discretionary action.

Respondent's Arguments

Respondent argues, in essence, that it did not comply with the ALJ's discovery order and directions to respond to CTP's request for documents because it did not want to expend the effort entailed in producing the requested documents so long as there remained a possibility that the ALJ might grant Respondent's admittedly untimely motion for a protective order. Respondent further asserts that the parties' and the ALJ's communications created uncertainty about the deadline for compliance with CTP's discovery request.

Specifically, Respondent argues that, although its February 26, 2015 motion for a protective order was "untimely," there "was still the potential for the [ALJ] to grant Respondent's motion" and that such ruling "was critical in determining what discovery [Respondent] would be required to produce." Respondent's Memorandum in Support of Notice of Appeal (R. Memo) at 2, 4 (unnumbered). Respondent states that, while it awaited a ruling on its motion to suppress, "CTP filed a motion for abeyance which further confused the matter." *Id.* at 4.

Respondent argues that "[u]pon receipt and review" of the ALJ's April 6, 2015 orders, which denied both Respondent's motion for a protective order and CPT's motion to hold deadlines in abeyance "but nonetheless extended the deadlines," *id.* at 2, Respondent telephoned the CRD staff attorney and learned that the case had been reassigned to another staff attorney. Respondent states that, on April 16, it telephoned the new staff attorney "to determine the discovery request deadline," and was told "that she needed to speak with the [ALJ] before answering Respondent's questions and providing clarification."⁷ *Id.*; *see* ALJ Decision at 3. Respondent asserts that, after it received the April 20 letter stating that the deadline to reply to CTP's discovery request remained March 2, 2015, it called the staff attorney on April 22 and emailed her on April 23 with "further questions."⁸ R. Memo at 2-3. Respondent reports that on April 23, after the staff attorney returned Respondent's telephone call "addressing remaining questions" Respondent had relating to the April 20 letter, it filed its "Response and attached documents to [CTP's] Request for Production." *Id.* at 3.

⁷ Respondent reports having called to speak to the staff attorney twice after receiving the ALJ's April 6, 2015 orders, the second time on April 16, 2015. R. Memo at 2. Respondent has not stated when it made the first call. The ALJ Decision and the April 20 letter issued at the ALJ's direction refer only to a phone call from Respondent's counsel on April 16, and Respondent does not allege having sought clarification of the April 6 orders any earlier than April 16, 2015.

⁸ Respondent in both its memorandum in support of its notice of appeal and its motion for the ALJ to reconsider the ALJ Decision states that it attached this April 23 email as its Exhibit 1. No such exhibit or email was filed with either pleading, however.

Respondent thus argues that "[a]ny delays in compliance with the [ALJ's] instructions" were "necessary" and "a direct result of awaiting the outcome of [Respondent's] pending motion [for a protective order] that could very well change the discovery Respondent was required to produce to Petitioner." *Id.* at 4. Respondent argues that the ALJ was not justified in striking Respondent's answer to the Complaint as a sanction for its failure to obey the ALJ's discovery instructions because Respondent "actively and in good faith communicated with [CTP] and [the DAB] several times in an attempt to resolve the matter [and] comply with the April 6, 2015 Order. *Id.* at 3. Respondent further argues that the sanction was unwarranted because "[a]s soon as Respondent was provided clarification, Respondent filed their response and resulting documents to [CTP's] RFP within five (5) days." *Id.*

Respondent asks the Board to apply "the maxims of equity [and] fairness" so as to not permit Respondent's "inadvertent miscalculation of discovery production procedure" to deny its request for a hearing. Notice of Appeal at 1.

<u>Analysis</u>

As discussed below, the Board reviews an action for which the regulation provides discretion to the ALJ, such as the imposition of sanctions, to determine whether the ALJ has abused that discretion and does not substitute its judgment for the ALJ's. For the reasons explained below, we conclude that the ALJ did not abuse her discretion in striking Respondent's answer to the Complaint and entering default judgment as a sanction for Respondent's failure to comply with the ALJ's repeated directions to respond to CTP's discovery requests. The record does not support Respondent's arguments that it was uncertain about the deadline for responding or had valid reasons for not timely responding and for not following the ALJ's directions. The untimely response that Respondent did file was, moreover, incomplete and continued to raise objections to CTP's request, in apparent defiance of the ALJ's ruling on the Respondent's protective order request.

I. <u>We review the ALJ's imposition of sanctions to determine whether the ALJ</u> <u>abused her discretion.</u>

The ALJ in sanctioning Respondent relied on the regulation stating that when a party fails to comply with a discovery order, "the presiding officer [i.e., the ALJ] may," among other sanctions, strike any part of the pleadings or other submissions of the party failing to comply with the discovery request. 21 C.F.R. § 17.35(c), *cited at* ALJ Decision at 4.

The Board "has long recognized that where the regulation states that an ALJ 'may' [for example] dismiss, dismissal is an exercise of discretion and reviewable as such." *Meridian Nursing & Rehab at Shrewsbury*, DAB No. 2504, at 8 (2013), *aff'd Meridian Nursing & Rehab at Shrewsbury v. Ctrs. for Medicare & Medicaid Servs.*, 555 F. App'x

177 (3rd Cir. 2014); *see* 42 C.F.R. §§ 498.40(c)(2), 498.69, 498.70 (ALJ "may dismiss" hearing request for specified reasons and "may extend" the time for filing a hearing request for good cause in appeals of certain agency actions relating to Medicare). The Board has accordingly held that "[t]he standard of review for an ALJ's exercise of discretion to dismiss a hearing request where such dismissal is committed by regulation

to the discretion of the ALJ is whether the discretion has been abused." *St. George Health Care Ctr.*, DAB No. 2645, at 3 (2015), *citing High Tech Home Health, Inc.*, DAB No. 2105, at 7-8 (2007), *aff'd*, *High Tech Home Health, Inc. v. Leavitt*, Civ. No. 07-80940 (S.D. Fla. Aug. 15, 2008); *accord Osceola Nursing & Rehab. Ctr.*, DAB No. 1708, at 2 (1999); *see also Waterfront Terrace, Inc.*, DAB No. 2320 (2010) (applying the abuse of discretion standard in reviewing an ALJ's finding that no good cause existed to justify an extension of time for filing a hearing request under section 498.40(c)(2)).

Under an "abuse of discretion" standard, "the reviewer may not simply substitute his or her judgment for that of the person exercising discretion." *Vincent Baratta, M.D.*, DAB 1172, at 9 n.5 (1990). Instead, the reviewing body – here the Board – will consider only whether the decision maker has articulated a reasonable basis for the decision under review, not whether it was the <u>only</u> reasonable decision. *River East Econ. Revitalization Corp.* DAB No. 2087, at 9 (2007) (in applying an abuse of discretion standard, the Board "will not substitute our judgment" for that of the agency rendering the challenged decision and will instead ask "only whether the agency has articulated a reasonable basis for its decision, not whether it was the only reasonable decision").

We accordingly consider whether the ALJ abused her discretion in striking Respondent's answer to the Complaint and entering default judgment against Respondent based on CTP's allegations. As we explain below, we conclude that the ALJ did not abuse her discretion and that she provided a reasonable basis for her determination.

II. <u>The ALJ did not abuse her discretion in striking Respondent's answer to the</u> <u>Complaint and entering default judgment against Respondent.</u>

For the reasons discussed below, we conclude that the record leading to the ALJ's imposition of sanctions reasonably supports a finding that Respondent's repeated failures to comply with the ALJ's directions to respond to CTP's request for documents were not simply the result of inadvertence or any reasonable uncertainty about the requirement to respond. The record instead evidences willful disregard of the deadlines that the ALJ clearly and repeatedly stated.

A. The ALJ clearly informed Respondent of the deadlines for discovery and repeatedly warned Respondent that failure to comply could result in sanctions including the striking of its answer.

The ALJ's PHO setting out the procedures for the appeal stated that the parties had to provide requested documents within 30 days of a request and, if they objected to the request, file a motion for a protective order within 10 days of the request. PHO at 7. The PHO also that warned that sanctions for failure to comply with the ALJ's orders could include dismissal of Respondent's answer. *Id.* at 8. The ALJ's order denying Respondent is motion for a protective order, dated April 6, 2015, further "direct[ed] Respondent to comply with CTP's discovery requests" and again warned that the ALJ "may impose penalties on Respondent, including dismissing its hearing request and entering a default judgment in favor of CTP, if Respondent fails to comply." Order Denying R. Motion for Protective Order at 2; *see* ALJ Decision at 3 (ALJ on April 6, 2015 "denied Respondent's Motion for a Protective Order and directed Respondent to comply with CTP's discovery requests [and] reiterated that the pre-hearing exchange deadlines were extended for both parties by 45 days from the initial deadline").

Then, ten days later on April 16, Respondent, instead of providing the documents CTP requested as the ALJ directed, phoned CRD ostensibly to determine the deadline for responding. On April 20, the staff attorney at the ALJ's direction reminded Respondent of the deadline for providing the requested documents. Ltr. Apr. 20, 2015, at 2 (requested documents due "30 days after the request has been made . . . Respondent had until March 2, 2015, given that the 30th day was a Saturday, to reply to CTP's discovery request"). The letter again warned Respondent of the possible sanctions for failing to comply, stating that the ALJ–

has the authority to sanction any party or counsel for failing to comply with discovery requests. In this case, Respondent has failed to comply with CTP's discovery requests. [The ALJ] may draw an inference in favor of CTP with regard to the information sought in its discovery request; prohibit Respondent from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and strike any part of the pleadings or other submissions of Respondent. It is at the discretion of the Administrative Law Judge to issue sanctions that reasonably relate to the severity and nature of a party's failure to comply with discovery requests or any other misconduct.

Id. (emphasis added).

Thus, Respondent had ample notice of the deadline for responding to CTP's request for documents, of its failure to comply with that deadline or with the ALJ's order to comply, and of the potential consequences that could attend its ongoing failure to do so.

Respondent's assertion that it did not produce the requested documents because "there was still the potential for the [ALJ] to grant Respondent's motion" for a protective order, R. Memo at 2, also does not explain why, once the ALJ denied Respondent's motion on April 6, Respondent still did not produce <u>any</u> documents for nearly three weeks, until April 24, 2015. Respondent's statement that it then filed its "Response and attached documents to [CTP's] Request for Production," *id.* at 3, does not convey the true nature of its response. In fact, Respondent provided only seven documents; *see* CTP Motion to Impose Sanctions, Ex. 1 (CTP Request for Production of Documents). Significantly, Respondent continued to object to most of CTP's requests for documents despite the ALJ having already denied Respondent's motion for a protective order. Thus, even as of April 24, 2015, Respondent remained out of compliance with the ALJ's orders.

B. The record does not support Respondent's arguments that CTP's and the ALJ's statements during the appeal created uncertainty about the deadline to respond to CTP's request for documents.

The record does not support Respondent's claim that CTP's March 25, 2015 motion to hold certain deadlines in abeyance "confused the matter" of when Respondent was required to respond to CTP's discovery request. Respondent's claim does not fully describe the content of the motion. CTP's motion sought only to hold in abeyance "the deadline for submitting its [CTP's] pre-hearing exchange, and the remaining deadlines set forth in the [ALJ's] February 24 Order" granting CTP's motion for a protective order. Motion to Hold Deadlines in Abeyance at 2. The only deadlines the ALJ set in the February 24 order were the deadlines for the parties to file their pre-hearing exchanges. CTP's motion to hold deadlines in abeyance did not seek to stay or toll any other deadlines, including the deadlines for responding to discovery requests. Indeed, CTP in the motion pointed out that the response to its discovery request was already overdue, and CTP sought abeyance of the deadlines for the pre-hearing exchanges precisely so it would have sufficient time to review the documents Respondent was required to provide. Respondent agrees that, as the CTP motion states, Respondent's counsel advised CTP that he consented to the granting of the motion. R. Memo at 2. Thus, Respondent cannot credibly claim to have been confused by its intent and contents.

⁹ These documents consist of Respondent's 41-page employee handbook; forms for employees to acknowledge having read the handbook and having watched an Alcoholic Beverage Control training video; a blank form used to record employee misconduct and one form completed by an employee alleged to have sold cigarettes to a minor on June 10, 2013, and a completed "Employee Tobacco Agreement" form in which that employee agreed to adhere to state law forbidding tobacco sales to minors.

Similarly, Respondent's statement that the ALJ in denying CTP's motion to hold deadlines in abeyance "extended the deadlines" does not accurately characterize the ALJ's ruling. The ALJ extended *only* the deadlines for the parties to file their prehearing exchanges (to May 26, 2015 for CTP's pre-hearing exchange, and June 9, 2015 for Respondent's pre-hearing exchange, from April 8 and 25, respectively) and did not extend any discovery deadlines. The April 20 letter accordingly advised Respondent that the ALJ "has not extended Respondent's deadline to reply to CTP's discovery request. The discovery request deadline was March 2, 2015, and this deadline stands." Ltr. Apr. 20, 2015, at 2; *see* ALJ Decision at 4 ("[t]he deadline to produce documents requested by CTP was never extended . . . Only the pre-hearing exchange deadlines were extended, hence, the two April 6, 2015, orders and the April 20, 2015, letter - all three of which clearly and consistently stated that the pre-hearing exchange deadlines were extended").

On the same day, moreover, the ALJ also denied Respondent's untimely motion for a protective order and, in doing so, "direct[ed] Respondent to comply with CTP's discovery requests," noted that she had extended the deadlines for the pre-hearing exchanges, and warned that "I may impose penalties on Respondent, including dismissing its hearing request and entering a default judgment in favor of CTP, if Respondent fails to comply." ALJ Order Denying R. Motion for Protective Order at 2. Respondent points to nothing ambiguous in this order, or in any of the ALJ's other issuances which, as discussed above, extended only the deadlines for the parties' prehearing exchanges but not the deadlines for responding to discovery requests, ordered Respondent to respond to CTP's discovery request, and warned Respondent that if it did not respond it risked the imposition of sanctions including the striking of its pleadings.

Based on this record, we conclude that the ALJ did not abuse her discretion in sanctioning Respondent's ongoing failure to comply with the ALJ's directions by striking Respondent's answer to the Complaint. The regulations specifically authorize the ALJ to "[s]trike any part of the pleadings" of any party that "fails to comply with a discovery" order[.]" 21 C.F.R. § 17.35(c)(3). The ALJ moreover determined that the sanction "reasonably relate[d] to the severity and nature of the failure or misconduct," as the regulation requires. 21 C.F.R. § 17.35(b); ALJ Decision at 4 (finding "Respondent's failure to comply with discovery requests sufficiently egregious to warrant striking the answer and issuing a decision"). The ALJ in doing quoted CTP's statement that Respondent's actions "extremely prejudicial to CTP's ability to prepare its case for hearing, including preparing its pre-hearing exchange and determining whether to move for summary decision." ALJ Decision at 4, quoting CTP Memo in Support of Motion for Sanctions at 3 (also arguing that Respondent's failure to produce documents prejudiced CTP's ability to address Respondent's denial of the allegations and the numerous affirmative defenses and mitigating factors it asserted), CTP Reply in Support of Motion for Sanctions at 3 (documents Respondent provided did not "relate to its claim that the unlawful sales never took place or that it was not responsible for them [and] are only tangentially related to its claimed mitigating factors").

We recognize that the striking of its answer is a relatively harsh remedy, as Respondent argues, and that the ALJ could have elected to impose one of the lesser sanctions described in the regulations. Our role in reviewing the ALJ's exercise of discretion, however, is not to substitute our judgment for that of the ALJ. Instead, we determine whether the ALJ has abused that discretion by considering whether the ALJ has articulated a reasonable basis for the decision under review, not whether it was the only reasonable decision. Respondent here repeatedly failed to follow the ALJ's directions and claimed reasons for those failures that the record does not support, and the ALJ's determination and actions were fully consistent with the regulations. We accordingly find no basis to reverse the ALJ's determination to strike Respondent's complaint and granting default judgment.

Conclusion

For the reasons discussed above, we affirm the ALJ Decision and Order imposing a \$500 CMP on Respondent.

> /s/ Constance B. Tobias

/s/ Susan S. Yim

/s/

Leslie A. Sussan Presiding Board Member