

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

KKNJ, Inc. d/b/a Tobacco Hut 12
Docket No. A-16-21
Decision No. 2678
March 9, 2016

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

KKNJ, Inc. d/b/a Tobacco Hut 12 (Respondent) appeals the November 5, 2015 Initial Decision and Default Judgment of an Administrative Law Judge sustaining a \$5,000 civil money penalty (CMP) against Respondent. *KKNJ, Inc. d/b/a Tobacco Hut 12*, DAB CR4391 (2015) (ALJ Decision). The Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) filed a Complaint assessing the CMP 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 the CTP Complaint 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. For the reasons explained below, we conclude that the ALJ did not commit an abuse of discretion in striking Respondent's answer and entering default judgment, and we sustain the ALJ Decision.

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 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 that FDA imposes 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 FDA and Tobacco Retailers – Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* at 8-9 (June 2014).² As applicable here, the FDA will assess a CMP of up to \$5,000 in the case of a fifth violation within a 36-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 initiated this case before the ALJ by serving its Complaint on Respondent and filing it with the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB). The regulations require a respondent to 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 a protective order within 10 days of receipt of a request for production. 21 C.F.R. § 17.23(a), (d)(1). The ALJ may grant a motion for a protective order, in whole or in part, if he or she finds that the request for production is unduly costly or burdensome, will unduly delay the proceeding, or seeks privileged information. 21 C.F.R. § 17.23(d)(2).

¹ <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf> accessed March 8, 2016.

² <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf> accessed March 8, 2016.

The regulations authorize the ALJ to impose sanctions on any party for actions including “[f]ailing to comply with an order subpoena, rule, or procedure governing the proceeding . . .” 21 C.F.R. § 17.35(a). When a party “fails to comply with a discovery order” 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). Sanctions the ALJ imposes “shall reasonably relate to the severity and nature of the failure or misconduct.” 21 C.F.R. § 17.35(c)(3).

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 Background³

The CTP Complaint sent April 22, 2015 sought a CMP against Respondent (1) for selling tobacco products to a person younger than 18 years and (2) for 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) respectively. Complaint at 1-2. The Complaint stated that during an inspection on December 7, 2014 a minor was able to enter Respondent’s establishment and purchase a regulated tobacco product. *Id.* at 2. CTP’s cover letter enclosed the narrative report of an FDA investigator stating that on December 7, 2014 he conducted an investigation with a minor and observed an employee of Respondent’s establishment sell cigarettes to the minor without requesting, or seeing, any ID from the minor. The cover letter enclosed photographs of Respondent’s establishment and a labeled plastic evidence bag containing what the inspector said was the package of cigarettes the minor had purchased.

CTP based the \$5,000 CMP on the commission of five violations within a 36-month period. The two alleged violations at issue in the present case arose from the events on December 7, 2014. Three prior violations were the subject of an earlier CTP complaint against Respondent; Respondent admitted having committed those violations, as part of a November 2014 settlement agreement with CTP. *Id.* at 4-5. (The current Complaint

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.

recounts that Respondent had admitted “three violations of 21 C.F.R. Part 1140 within a twenty-four month period” on March 19, 2014 and September 10, 2013, including two violations of section 1140.14(a) and (b)(1) (barring tobacco sales to minors and requiring photo ID age verification). *Id.* at 3-4.)

Respondent’s answer to the current Complaint asked that it be dismissed for lack of evidence. Respondent also argued that the FDA’s enforcement process was flawed and unfairly threatened excessive penalties on small businesses that, like Respondent, trained its staff to obey the laws against selling tobacco to minors.

The ALJ by pre-hearing order (PHO) on June 29, 2015 ordered the parties to serve any requests for documents on each other by July 27, 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 a joint status report within 30 days addressing the possibility of settlement and set deadlines for them to file pre-hearing exchanges (briefs, witness and exhibit lists, proposed exhibits, and witness statements). *Id.* at 2-3. The ALJ warned the parties: “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.

CTP on September 2, 2015 filed motions to compel discovery and to extend the deadlines in the PHO, stating that it had received no response to CTP’s request for production of documents that it sent to Respondent on July 27, 2015, which CTP attached to its motions. The ALJ on September 3 gave Respondent until September 17, 2015 to file an objection to CTP’s motion to compel discovery and extended the deadlines for prehearing exchanges. Respondent’s objection, dated September 10, 2015, argued, among other grounds, that “I should not have to provide any of the documents they requested if I haven’t even been proven guilty,” that most of what CTP requested were public records or were irrelevant to the case, and that some documents did not exist or no longer existed.

The ALJ by order of September 18, 2015 stated that she had “considered Respondent’s objections” and found “no basis to deny CTP’s motion” to compel discovery. The ALJ ordered Respondent to “comply with CTP’s Request for Production of Documents by providing the documents sought” and warned that “[f]ailure to do so may result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty.” ALJ Order at 2 (Sept. 18, 2015). The order noted that the ALJ’s PHO had

provided “that a party receiving a production request has 10 days to file a protective order,” and the ALJ found “no evidence that Respondent has either provided the requested documents or requested a protective order.” *Id.* citing 21 C.F.R. § 17.23(d)(1). The ALJ also granted CTP’s motion to extend deadlines, giving CTP and Respondent until November 4 and 25, 2015, respectively, to file their pre-hearing exchanges. *Id.*

By a submission dated September 21, 2015 Respondent asked the ALJ to dismiss the case for lack of evidence, arguing that CTP “has not provided any evidence that has any merit but pictures of the outside of the store and pictures of a pack of cigarettes” and has “no evidence of being inside this store making this so called transaction.” On October 9, 2015, CTP filed a status report and motion to impose sanctions against Respondent for continuing to fail to respond to CTP’s request for production of documents despite the ALJ’s September 18, 2015 order that Respondent comply with the request. CTP asked the ALJ to strike Respondent’s answer to the Complaint and issue a default judgment imposing the \$5,000 CMP, arguing that based on “Respondent’s pattern of conduct” it was “unlikely that more time or additional orders in this proceeding will change the status quo.” CTP Status Report & Motion to Impose Sanctions at 2. The ALJ on October 15, 2015 gave Respondent until October 30, 2015 to file an objection to CTP’s motion for sanctions.

There then followed two filings from Respondent and one from CTP arguing over CTP’s motion for sanctions. Respondent, in an October 14, 2015 filing, asked the ALJ not to impose sanctions and to dismiss CTP’s case against “because the information they are requesting violates the privacy act” and because Respondent had not received discovery materials Respondent’s representative said CTP had agreed to provide when he requested them by phone. On October 27, 2015, CTP asserted it had “never been served with any discovery requests from Respondent,” noted that the regulations at 21 C.F.R. § 17.13(b) require personal service or service by mail, and requested “that the record reflect that Respondent never served discovery on Complainant within the time set forth” in the PHO. Respondent, in a filing dated October 22, 2015, asked the ALJ to deny the motion for sanctions and requested a protective order from CTP’s discovery request essentially on the grounds that it sought confidential information that could harm Respondent’s business if made public or disclosed to his competitors or his suppliers. Respondent also complained of the cost in lawyer and accountant fees of complying with the request, claimed there was “no concrete proof that this establishment sold any tobacco product to a minor,” and characterized CTP’s inspection process as an abuse of power.

On November 5, 2015, the ALJ issued her decision striking Respondent’s answer and entering default judgment sustaining the CMP.

The ALJ Decision

The ALJ recounted the chronology and substance of the parties' filings as described above. The ALJ then found that, during the hearing process, Respondent had "failed to comply with a judicial direction regarding CTP's discovery request" filed July 27, 2015 and further found "no evidence that Respondent filed a motion or made a request for a protective order within 10 days of receiving the July 27, 2015 request" for production from CTP, as required by the regulations and the PHO. ALJ Decision at 1, 2. The ALJ noted that Respondent's October 22, 2015 request for protective order "is made more than two and a half months beyond the statutory deadline of August 6, 2015."⁴ *Id.* at 3. The ALJ ruled that "[d]ue to noncompliance with my Order granting CTP's Motion to Compel, I am striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true." *Id.* citing 21 C.F.R. § 17.35(c)(3), 17.11(a). The ALJ recognized that the "harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply," and expressly found "the failure to comply here sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *Id.*, citing 21 C.F.R. § 17.35(b).

The ALJ then recited the facts alleged in the CTP Complaint (and summarized above) that she assumed as true. Those facts included the FDA investigator's report of having witnessed the minor purchase cigarettes from Respondent's establishment on December 7, 2014 without being asked for photo ID, and the accompanying photos of Respondent's establishment and the package of cigarettes in a labeled evidence bag.⁵ The facts also included information about Respondent's settlement of the prior complaint for three violations in March 2014 and September 2013, including the CRD docket number assigned to that complaint when CTP filed it with CRD. The ALJ concluded that these

⁴ The ALJ Decision identifies Respondent's request for a protective order as a letter of October 23, 2015. Respondent's letter was dated October 22, 2015, as noted earlier, but was postmarked October 23.

⁵ The first paragraph of the ALJ Decision describes the CTP Complaint as alleging that Respondent "impermissibly . . . used a self-service display in a non-exempt facility," in addition to the two violations of selling cigarettes to a minor and not verifying the purchaser's age. ALJ Decision at 1. The regulations prohibit "vending machines and self-service displays" unless "located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time." 21 C.F.R. § 1140.16(c)(1), (c)(2)(ii). The current Complaint, however, does not allege a self-service display violation. Instead, the earlier, settled complaint states that on September 10, 2013 an FDA-commissioned inspector observed at Respondent's establishment the use of "a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c)." CRD Docket No. C-14-1985 Complaint at 3 (filed Oct. 7, 2014), Notice of Settlement Agreement (filed Nov. 17, 2014). The ALJ's mistaken attribution of the "self-service display" violation to the instant CTP Complaint rather than the prior complaint does not affect the amount of the CMP that CTP may impose, as Respondent is still liable for five violations within a 36-month period.

facts established Respondent's liability under the Act and regulations and that a \$5,000 CMP, the amount CTP imposed, was permissible under 21 C.F.R. § 17.2 (CTP imposes CMP of up to \$5,000 in the case of a fifth violation within a 36-month period). *Id.* at 5-6.

Respondent's Arguments

Respondent attributes its failure to respond to the ALJ's order to comply with CTP's discovery to confusion caused by CTP's response to the phone call Respondent reported making to CTP seeking discovery. Notice of Appeal (NA) at 3 ("the phone call between the respondent and CTP . . . caused such confusion of this case" and "not doing things in a timely manner"). Respondent states, apparently in response to CTP's assertion before the ALJ that CTP had not been served with any discovery requests, that "[t]he phone call did happen," and that, during the call, CTP stated that Respondent "already had" CTP's evidence "which was the pictures that they sent" Respondent. *Id.* at 2-3. Respondent also argues that the failure to respond to CTP's discovery request did not merit a sanction as harsh as the ALJ imposed because the discovery request was "over the top," sought information CTP did not need, and was an attempt to force Respondent to admit the violations. *Id.* at 3 ("this was done so they would force your hand to admit guilt"). Respondent also asserts that the ALJ erroneously based the default judgment on the prior CTP complaint that Respondent settled by admitting three prior violations.

Analysis

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. 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.

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

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 3.

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 regulations providing hearings for Medicare nursing facilities sanctioned for noncompliance with regulations governing quality of care).

Thus, the question before us is not whether Respondent could have prevailed had the case gone to hearing or whether Respondent would have been entitled to a protective order against discovery had Respondent sought one when required by the PHO, but 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.

II. The ALJ did not abuse her discretion in striking Respondent’s answer to the Complaint and entering default judgment against Respondent.

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, they had to file a motion for a protective order within 10 days of the request. PHO at 7. The PHO also warned that sanctions for failure to comply with the ALJ’s orders could include dismissal of Respondent’s answer to the CTP complaint. *Id.* at 8. The ALJ’s order of September 18, 2015 granting CTP’s motion to compel discovery and finding no basis for Respondent’s objections to discovery ordered that “by October 5, 2015, Respondent shall comply with CTP’s Request for Production of Documents by providing the documents sought,” thus granting Respondent a substantial extension of time to respond to CTP’s discovery request. Order at 2 (Sept. 18, 2015). The order again warned Respondent that “[f]ailure to do so may result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty.” *Id.* Respondent does not allege that it did not understand these clearly-stated deadlines or the sanctions that the ALJ could impose for failing to follow them. Nor does Respondent offer, either to the ALJ or on appeal, any explanation of events that prevented it from timely responding or

timely seeking a protective order. Thus, Respondent had ample opportunity to produce the documents and ample notice of the deadline for responding to CTP's request for documents and of the possibility that failing to do so could result in the ALJ dismissing Respondent's answer to the complaint.

Respondent does not dispute that, notwithstanding the clear notice of the deadlines to respond to the discovery request or to seek a protective order and of the consequences of failing to provide the requested documents, it did not object to CTP's document request within 10 days and did not produce the documents within 30 days, as the PHO required. Respondent also does not deny that it continued not to provide any of the requested documents, even after the ALJ denied Respondent's objection to discovery (filed after the deadline in the PHO for a protective order, which the ALJ extended), and even after the ALJ twice warned of the possible consequences for failing to comply with her order. Respondent continued to file letters with the ALJ complaining about CTP's discovery request and its case against Respondent but simply ignored the ALJ's order to provide CTP the documents it requested. *See, e.g.*, R Ltr. (Sept. 21, 2015).

Respondent's explanation that it did not comply with the request for documents because of "confusion" raised by Respondent's reported phone call with CTP is disingenuous.⁶ Respondent states that the purpose of the call was for Respondent to obtain CTP's evidence and has stated both that CTP in the call promised to provide the evidence but did not do so, and that CTP said it had already provided the evidence in the form of the photos enclosed with the CTP complaint. R. Resp. to CTP Motion for Sanctions (Oct. 14, 2015); NA at 2. Respondent does not allege that the call addressed CTP's own request for documents or that any statements by CTP could have led Respondent to believe it was permitted to deviate from the ALJ's clear deadlines for Respondent to produce the documents CTP requested or to object to the document request. In short, a call discussing documents that Respondent wished to receive from CTP cannot explain Respondent's failure to respond in any way to CTP's formal document request to Respondent.

Moreover, even if we accepted (which we do not) that the call somehow confused Respondent about its responsibility to act promptly on CTP's document request, we cannot find any basis for a claim that this call could have justified Respondent ignoring

⁶ Respondent is mistaken in its assertions that CTP denies that any such phone call occurred; rather, CTP argued only that it had "never been served with any discovery requests from Respondent." CTP Reply Regarding Motion to Impose Sanctions at 1 (Oct. 27, 2015). Respondent asserts that the phone call was with "CTP" (or "they" or "them") and does not identify any individual with whom its representative purportedly spoke or allege that its representative spoke to CTP counsel. NA at 3; R. Resp. to CTP Motion for Sanctions (Oct. 14, 2015).

the ALJ's subsequent repeated orders that Respondent produce the requested documents. The ALJ's repeated warnings that Respondent's failure to comply with the deadlines set in those orders could lead to the very sanction ultimately imposed were entirely unambiguous.

Respondent also alleges that the ALJ erroneously based the default judgment on Respondent's admission, in settling the earlier CTP complaint, of having committed three prior violations of the regulations governing the sale of tobacco products. Respondent depicts ALJ Decision as "saying that . . . by signing the Acknowledgment form on Nov 6th 2014 for a violation that took place here on March 19th 2014 that I the respondent must be guilty on this case that supposedly happened on Dec 7th 2014." NA at 3. Respondent here refers to the ALJ's finding that Respondent's representative, on November 6, 2014, "signed an Acknowledgment Form in which he 'admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that violations may be counted in determining the total number of violations for purposes of future enforcement actions.'" ALJ Decision at 4.

Respondent does not dispute having admitted to the three prior violations that were the subject of the earlier complaint that CTP and Respondent settled. Respondent appears to have misunderstood the point of the ALJ's recitation of undisputed facts of the earlier complaint and its settlement. The ALJ's conclusion that Respondent committed the violations on December 7, 2014, was based on the evidence in the record. Those violations were undisputed because Respondent's answer was stricken from the record as a sanction.⁷ ALJ Decision at 4. The prior violations were relevant because the repeated violations established the basis for the amount of penalty imposed, not as proof of the more recent violations. Respondent has not shown any error in the ALJ's findings.

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 followed the requirement of the regulations that a sanction "reasonably relate to the severity and nature of the failure or misconduct." 21 C.F.R. § 17.35(b). As the ALJ explained, she considered the appropriateness of the sanction, and concluded that Respondent's failure to comply with her orders was "sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings." ALJ Decision at 3, citing 21 C.F.R. § 17.35(b). The ALJ could reasonably conclude that, as CTP argued, sanctions short of striking

⁷ Striking the answer left Respondent in the position of not having answered the Complaint, upon which the ALJ "shall assume the facts alleged in the complaint to be true" and, if such facts establish liability, issue a decision imposing the smaller of the maximum CMP provided in the Act and regulations, or the amount CTP sought, which is what the ALJ did here. 21 C.F.R. § 17.11(a).

Respondent's answer would have been unlikely to result in Respondent complying with the ALJ's orders to provide the documents CTP requested.

We recognize, as did the ALJ, that striking Respondent's answer is a relatively harsh remedy, as Respondent states. NA at 3. Our role, however, is to determine whether the ALJ's decision to impose that remedy was outside the bounds of her discretion. Given Respondent's deliberate, ongoing refusal to comply with the ALJ's orders to provide the requested documents, or to timely move for a protective order, while knowing of the sanctions the ALJ could impose, we decline to conclude that the ALJ abused her discretion in striking Respondent's answer to the Complaint. We accordingly find no basis to reverse the ALJ's determination to strike Respondent's Complaint and grant default judgment.

Conclusion

For the reasons discussed above, we affirm the ALJ Decision imposing a \$5,000 CMP on Respondent.

/s/
Christopher S. Randolph

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member