In the United States Court of Federal Claims

BID PROTEST
No. 15-1015C
(Filed Under Seal: February 12, 2016 | Reissued: February 25, 2016)[*]

AvKARE, INC.,	)	Keywords: Bid Protest; Contract Disputes Act; Requests for Modification; Federal Supply Schedule; 48 C.F.R. § 515.408; Commercial Sales Practices; Interpretation of Regulations; Plain Meaning; Lack of Good Faith; De Facto Debarment.
Plaintiff,	)	
v.	)	
THE UNITED STATES OF AMERICA,	)	
Defendant.	)	

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James W. Poirier, Trial Attorney, with whom were *Benjamin C. Mizer*, Principal Deputy Assistant Attorney General, *Robert E. Kirschman, Jr.*, Director, and *Martin F. Hockey, Jr.*, Assistant Director, Commercial Litigation Branch, United States Department of Justice, Washington, DC, for Defendant.

OPINION AND ORDER

KAPLAN, Judge.

This hybrid pre-award bid protest and breach of contract action is before the Court on the parties' cross-motions for judgment on the administrative record. The plaintiff in the case, AvKARE, Inc., is in the business of purchasing pharmaceutical products in bulk from their manufacturers for purposes of repackaging and selling them under the "AvKARE" label. AvKARE currently holds a Federal Supply Schedule (FSS) contract with the Department of Veterans Affairs (VA) for the sale of such pharmaceuticals. It brought this action to challenge: 1) the VA's refusal to grant requests for modification of its existing FSS contract that would permit AvKARE to add certain

[*] This Opinion was originally issued under seal, and the parties were given the opportunity to request redactions. Neither party requested redactions, and the opinion is now being reissued in full.

drugs to the FSS; and 2) its refusal to take further action on AvKARE's proposal to renew its contract.

The VA has refused to process the RFMs or give further consideration to AvKARE's renewal offer because AvKARE has declined to provide the VA certain commercial sales practice (CSP) information about the suppliers of the pharmaceuticals that AvKARE sells. According to the government, pursuant to 48 C.F.R. § 515.408(b), which is incorporated into the Schedule 65 I B solicitation, AvKARE must provide CSP information about its suppliers because AvKARE is a "dealer/reseller" of the pharmaceuticals. AvKARE contends, however, that it is not a "dealer/reseller." Rather, according to AvKARE, it is the "manufacturer" of the pharmaceuticals and, in any event, it was not required to provide its suppliers' CSP data because its own sales of its pharmaceutical products to the public are significant.

For the reasons set forth below, the Court concludes that it lacks jurisdiction over AvKARE's claims concerning the denial of its requests for modification because AvKARE failed to file a claim with the contracting officer as is required to invoke this Court's jurisdiction under the Contract Disputes Act. Those claims, accordingly, are **DISMISSED**.

With respect to AvKARE's bid protest, the Court concludes that under the applicable regulations AvKARE is not a "manufacturer" of the pharmaceutical products it is offering for sale. Rather, it is a "dealer/reseller." As such, the VA's decision to give no further consideration to AvKARE's offer in the face of AvKARE's flat refusal to provide manufacturers' CSP data was neither arbitrary, capricious, nor contrary to law. It further concludes that the VA acted well within its discretion when it concluded that AvKARE's sales of its products to the public were not significant. Finally, it concludes that the VA did not exhibit bad faith in considering AvKARE's proposal and did not effect a de facto debarment of AvKARE from future VA contracts. Therefore, the government's motion for judgment on the administrative record is **GRANTED** and AvKARE's cross-motion is **DENIED**.[1]

BACKGROUND

I. The VA's Pharmaceutical Procurement Process

As the operator of the nation's largest integrated health care system, the VA is a major purchaser of pharmaceuticals. See U.S. Gov't Accountability Office, GAO 13-358, Prescription Drugs[:] Comparison of DOD and VA Direct Purchase Prices, at 4 (Apr. 2013) (stating that "[i]n fiscal year 2012, VA's prescription drug spending totaled about $4.2 billion"). To meet its needs and achieve economies of scale, the VA, under a delegation from the General Services Administration (GSA), administers an FSS contract vehicle—Schedule 65 I B—through which it establishes firm-fixed prices with

[1] AvKARE's second motion to supplement the administrative record is likewise **DENIED** for the reasons set forth below.

pharmaceutical suppliers. See VA Schedule Program Overview, U.S. Department of Veterans Affairs (2014), www.va.gov/oal/docs/business/nac/fss ContractorOverviewLibrary.zip; Schedule 65 I B Drugs, Pharmaceuticals, & Hematology Related Products, U.S. Department of Veterans Affairs, http://www.va.gov/oal/business/fss/pharmaceuticals.asp (last visited February 11, 2016). Individual VA customers (such as VA hospitals) and other federal purchasers can then place orders directly with the supplier to meet their particular needs. See VA Schedule Program Overview, supra, at 4.

Several offices within the VA play a role in the pharmaceutical acquisition program. See Doing Business with VA, U.S. Dep't of Veterans Affairs, at 17 (Dec. 2015), http://www.va.gov/osdbu/docs/doingBusinessWithVA_ReferenceGuideFULL.pdf. At the top level, the VA's Office of Acquisition and Logistics (OAL) oversees the contracting process and "provides comprehensive acquisition support" for all of the VA's healthcare services and products. Id.; see also Office of Acquisition and Logistics (OAL), U.S. Dep't of Veterans Affairs, http://www.va.gov/oal/ (last visited February 11, 2016). Within OAL, the VA's National Acquisition Center (NAC) "supports [the] health care requirements of VA and other government agencies" by awarding and managing the variety of acquisition and delivery contracts that connect suppliers with government purchasers. Doing Business with VA, supra, at 17; see also National Acquisition Center, U.S. Dep't of Veterans Affairs, http://www.va.gov/oal/about/nac.asp (last visited February 11, 2016).[2] The VA's Federal Supply Schedule Service, in turn, manages the NAC's multiple award schedule (or FSS) contracts, including the schedule contract for pharmaceuticals. Doing Business with VA, supra, at 17; see also VA Federal Supply Schedule Service, U.S. Dep't of Veterans Affairs, http://www.fss.va.gov/ (last visited February 11, 2016). Finally, the VA's Office of the Inspector General (OIG) has a dedicated Office of Contract Review that "provide[s] preaward, postaward, and other requested reviews of vendors' proposals and contracts." See About the Office of Contract Review, U.S. Dep't of Veterans Affairs, http://www.va.gov/oig/about/contract-review.asp (last visited February 11, 2016).

II. The Schedule 65 I B Solicitation

The VA maintains its Schedule 65 I B solicitation on a perpetually-open basis. See Administrative Record (AR) Tab 1 at 5–8 ("Read Me First" document describing the process for obtaining a contract); id. Tab 2 at 84 (describing the "Consideration of Offers Under [the] Standing Solicitation"); see also Getting on Schedule, U.S. Dep't of Veterans Affairs, http://www.va.gov/oal/business/fss/gettingOnSchedule.asp (last visited February 11, 2016).[3]

[2] Other government agencies (such as the Department of Defense) may also place orders on contracts administered by the NAC. See National Acquisition Center, supra; VA Schedule Program Overview, supra, at 4.

[3] The Schedule 65 I B solicitation is periodically updated, with the most recent update released on February 19, 2014. See AR Tab 2 at 13. The solicitation has also since been amended twice (on September 30, 2014, and December 31, 2014), but neither amendment

Pursuant to the solicitation, after receiving an offer, the VA conducts an initial review and, if necessary, "asks for clarifying or additional information." AR Tab 1 at 8. Once it has received any additional information, the VA "conducts a price analysis and fully evaluates the proposal" before beginning price negotiations. See id. Through this process, the VA aims to "ensure the vendor is responsible" and that "the Government is receiving a fair and reasonable price."[4] Id.

According to the solicitation, "Contracting Officers determine whether prices are fair and reasonable by comparing the prices/discounts that a company offers the government with the prices/discounts offered to commercial customers." AR Tab 1 at 3. To make this comparison, in accordance with GSA regulations that apply government-wide, see 48 C.F.R. § 501.101, the VA "requires offerors to furnish commercial pricelists and disclose information regarding their commercial pricing/discounting practices." AR Tab 1 at 3. This information is known as the offeror's Commercial Sales Practice (CSP) information.

Pursuant to 48 C.F.R. § 515.408, the solicitation requires offerors to disclose several types of CSP information. See AR Tab 5 at 197–204. First, the offeror must provide information about the prices it charges certain commercial customers for the same products it wishes to sell to the government.[5] Id. at 198. Second, the offeror must disclose the amount of its sales to the general public for the previous year and its projected annual sales to the federal government during the life of the contract. AR Tab 4 at 200–01.

Further, as provided by 48 C.F.R. § 515.408(b)(5), the solicitation requires additional CSP information from any offeror who is a "dealer/reseller without significant sales to the general public"—i.e., any offeror who is not a "manufacturer" and lacks significant commercial sales. Id. at 202. Such dealer/resellers must provide

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is relevant to this case. See 65IB Drugs, Pharms. & Hematology Related Prods. Solicitation Refreshment - M5-Q50A-03-R7, Federal Business Opportunities, https://www.fbo.gov/index?s=opportunity&mode=form&id=aa3281f6d159d44c0614ee642186758e&tab=core&_cview=1 (last visited February 11, 2016).

[4] Although the firm-fixed prices agreed upon in these negotiations are considered "fair and reasonable," government purchasers may (and, in many cases, must) conduct a second round of independent price negotiations when placing orders off the schedule. See FAR 8.404(d) ("Although GSA has already negotiated fair and reasonable pricing, [purchasers] may seek additional discounts before placing an order."); id. 8.405-4 ("[Purchasers] may request a price reduction at any time before placing an order . . . . However, the [purchaser] shall seek a price reduction when the order . . . exceeds the simplified acquisition threshold.").

[5] Specifically, for each item the offeror wishes to sell, it must disclose the prices it charges to both the offeror's Most Favored Customer and also to a so-called "tracking customer." See AR Tab 5 at 198.

"manufacturers' [CSP] information . . . for each item/SIN offered, if the manufacturers' sales under any resulting contract are expected to exceed $500,000." Id. According to the solicitation, "[t]he information is required in order to enable the Government to make a determination that the offered price is fair and reasonable." Id.

In a separate section, the solicitation provides more guidance for dealer/resellers on providing manufacturers' CSP information. See AR Tab 12 at 491–505. These additional instructions explain that:

> [O]fferors who are dealers or resellers must provide the [manufacturers' CSP] information . . . when both of the following two criteria are met:
>
> > (1) When the offeror does not have "significant sales" to the general public[,] [a]nd
> >
> > (2) When the total value of the manufacturer's [sic] sales by the offeror for the proposed products is expected to exceed $500,000 for the contract term.

Id. at 503 (emphasis in original). Moreover, the instructions continue, "[t]he reference to 'significant sales' is not defined as it is examined on a case by case basis." Id.

In addition, and as pertinent to this case, the solicitation includes clauses governing modifications to the contract. AR Tab 2 at 53–56. These clauses set forth procedures for adding and deleting products from the schedule and for requesting price increases or offering price decreases. See id.; see also Modifying Your VA FSS Contract, U.S. Department of Veterans Affairs, http://www.va.gov/oal/business/fss/rfmProcess.asp (last visited February 11, 2016). The clauses specify that all requests for modification (RFM) must be submitted to the contracting officer (CO) for review, and that vendors requesting modifications must provide CSP information for the affected products—including, if the vendor is a dealer/reseller, manufacturers' CSP information. AR Tab 2 at 53. The VA's goal is "to review all modification requests and make an award/no award decision within 60 calendar days from receipt." Modifying Your VA FSS Contract, supra.

III. AvKARE's Existing Schedule 65 I B Contract

AvKARE's business consists of selling a "variety of bottled and unit dose pharmaceutical products" that are "packaged and sold under the 'AvKARE' label." Compl. at 1. Specifically, AvKARE obtains "bulk" pharmaceutical products from suppliers and then "repackage[s] and re-label[s]" them for sale "under its own private label . . . . . utilizing National Drug Codes (NDCs) assigned by the FDA to AvKARE and

only AvKARE." Compl. ¶¶ 55–56; see also Transcript of Hearing at 19:18–20:10 (Sept. 17, 2015) (counsel for AvKARE explaining AvKARE's business model).[6]

AvKARE was first awarded a Schedule 65 I B contract in April 2010. Compl. ¶ 49; AR Tab 171 at 20950. At that time, according to AvKARE, the company lacked significant commercial sales of its products. Compl. ¶ 49. The contract was originally slated to expire on March 31, 2015, and AvKARE submitted an offer to renew the contract on October 31, 2014. Id. ¶ 44; see also AR Tabs 13–24. The parties have since agreed to extend AvKARE's existing contract, first through January 31, 2016 and then again through the end of February 2016. Pl.'s Mem. in Supp. of its Mot. for J. on the Admin. R. ("Pl.'s Mem.") at 10, ECF No. 29.

IV. The OIG's Post-Award Review of AvKARE's Contract and the VA's Denial of AvKARE's RFMs

Between 2010 and 2014, AvKARE submitted numerous RFMs to add new drugs to its contract. Compl. ¶ 50. According to AvKARE, these RFMs were routinely granted. Id. Sometime in early 2014, however, the OIG began a post-award review of AvKARE's contract.[7] See AR Tab 171 at 20950. On August 27, 2014, the OIG updated the CO on the status of its investigation. Id. The OIG's "preliminary findings" included concerns that AvKARE "misrepresented that they had commercial sales in order to obtain their FSS contract" and "misrepresented that they are a pharmaceutical manufacturer" Id. In light of the ongoing investigation, the OIG recommended that "any request(s) to add product(s) to the contract, between now and March 31, 2015, be submitted to our office for a preaward review" and that "no extension [of the contract] be exercised prior to our office conducting a preaward review." Id. (emphasis in original). At this time, according to AvKARE, it had at least three outstanding RFMs. Compl. ¶ 65.

In mid-September 2014, the OIG conducted an on-site review at AvKARE's purported production facilities. Compl. ¶¶ 63–64; see AR Tab 173 at 20954. Afterwards, on October 6, 2014, the OIG informed the CO that it had completed a review of one of AvKARE's outstanding RFMs. AR Tab 173 at 20954–55. First, the OIG reported, AvKARE was considered a "distributor of the offered products, not the manufacturer" because "[t]he offered products are never in the possession of AvKARE throughout the process." Id. at 20954. Instead, the products were "shipped in bulk containers from the

[6] According to AvKARE, "[o]nce an NDC is assigned by the FDA to AvKARE for a specific product, AvKARE and only AvKARE is entitled to [sell] products . . . on the basis of that NDC." Compl. ¶ 28.

[7] This investigation was apparently sparked in part by an anonymous tip describing alleged violations of the contract's CSP provisions. See AR Tab 188 at 21058.

manufacturer of the product" to a non-AvKARE packager, packaged, and then shipped to another non-AvKARE entity for distribution. Id.

In addition, the OIG determined that AvKARE did not have relevant commercial sales, and thus the "manufacturer's [sic] full CSP data is required." Id. According to the OIG, AvKARE "expressed their disagreement with the requirement" because "there would be no way to get CSP data that is relevant," as "they package the product in different quantities than are commercially available from the manufacturer." Id. The OIG "totally disagree[d] with AvKARE's opinion," believing that "CSP data should be required from the manufacturer which represents the nearest commercially available package size of the products offered." Id.

V. AvKARE's Contract Renewal Offer

All told, AvKARE alleges that it submitted at least six more RFMs between October 2014 and September 2015. See Compl. ¶¶ 67, 69–70. AvKARE claims that all these RFMs either remain under review or have been rejected by the VA. See id.

As mentioned above, AvKARE submitted a contract renewal offer on October 31, 2014. Id. ¶ 44; see AR Tabs 13–24. In response to the solicitation's "Company Information" questionnaire, AvKARE identified its "Type of Business" as "Manufacturer" and stated that its facilities included 57,000 square feet of manufacturing floor space. AR Tab 13 at 510.

In response to Clause AS8005 of the solicitation, which requests information about the "manufacturing facilities/place of performance" for each of the offeror's products, see AR Tab 4 at 175–80, AvKARE also represented that it was "the manufacturer . . . of the products offered on this solicitation."[8] Id. at 526. On the other hand, AvKARE included a purported "Letter of Supply" with its offer, AR Tab 18 at 585, apparently in response to Clause I-FSS-644 of the solicitation, which requires offerors who are "dealers and suppliers"—i.e., offerors "other than the manufacturer"—to produce "letter[s] of supply/commitment" from the products' manufacturers upon the CO's request. AR Tab 4 at 181. These letters must "assure the offeror of a source of supply sufficient to satisfy the Government's requirements for the contract period." Id.

[8] The substantive purpose of Clause AS8005 is to ensure compliance with the FDA's Current Good Manufacturing Practice (CGMP) regulations. See AR Tab 4 at 175–80. These regulations describe the acceptable "methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." 21 C.F.R. § 210.1(a). Clause AS8005 specifically requests information about the "location and owner of [the] facility where [the] ingredients are measured, weighed, mixed and compounded;" the "location of facilities where intermediate containers will be fixed and labeled;" and the "location of facilities where products will be packed and prepared for shipment." AR Tab 4 at 178–80.

The letter AvKARE submitted, addressed to "AvKARE," and from "AvKARE, Inc.," represented that "[i]n the event AvKARE is awarded a . . . contract . . . AvKARE, Inc. can assure an uninterrupted source of supply, with sufficient quantities of product, for the duration of the . . . contract period." AR Tab 18 at 585.

Most relevant to this case, in responding to the solicitation's pricing and price evaluation provisions, AvKARE did not include CSP information about the manufacturers who supply AvKARE with the pills that it repackages and sells to the VA as would be required of a dealer/reseller without significant sales to the general public. See AR Tab 22; see also id. Tab 23 at 601 (beginning a description of AvKARE's sales process with the phrase "As a drug manufacturer . . . ").

VI. VA Requests for Additional Information

On December 24, 2014, the CO contacted AvKARE to request additional information. AR Tabs 341–48. This request primarily took the form of a "Missing Information Checklist." AR Tab 344 at 21600–10. "Upon receipt of all requested items identified on the Missing Information Checklist," the CO explained, "we can move forward with a continued review of your offer." AR Tab 341 at 21595.

First, the CO requested that AvKARE "[p]lease clarify what is produced on the premises" of AvKARE's manufacturing facility and that it clarify its basis for claiming that it had an estimated 57,000 square feet of manufacturing space. AR Tab 344 at 21600 (quotation omitted). Further, the CO asked AvKARE to "specifically delineate what AvKARE does with [its] drugs after receipt" and to "[p]rovide documentation that explains which entities obtain title to and possession of the product" and "outline what each entity does to the drug." Id. at 21602.

The CO also requested that, in response to Clause I-FSS-644, AvKARE "[p]lease provide requisite Letters of Supply" in accordance with that clause's requirements for dealers and resellers. Id. The CO noted that AvKARE's letter "to itself . . . from (itself)" was "not accepted." Id.

Next, the CO informed AvKARE that the CSP information it provided was not fully responsive to the solicitation's requirements. See id. at 21606–09. In response to the solicitation's request for information regarding "sales to the general public," the CO noted that "[s]ales to federal entities via a wholesaler are not considered commercial sales." AR Tab 344 at 21606. Rather, "[t]hose sales are indirect sales to federal entities." Id. Accordingly, the CO requested that AvKARE revise its submission so that "only sales to commercial end users [are] reflected." Id.

Further (and as most relevant here), the CO informed AvKARE that "[m]anufacturer information for each item/SIN offered[] is required" under the CSP provision for dealer/resellers because "AvKARE commercial sales as a percent of government sales are considered insignificant" and "expected sales under any resulting contract are expected to exceed $500,000." Id. at 21608.

VII. AvKARE's Response to VA Requests for Additional Information

On January 16, 2015, AvKARE responded to the CO's request for additional information. See AR Tab 360. AvKARE continued to maintain that it was the "manufacturer" of the products it wished to sell because it "produces and manufactures its own private label generic pharmaceuticals." Id. at 21671; see also id. at 21672 ("AvKARE reaffirms its selection as manufacturer . . . . . We are the manufacturer."). To bolster this contention, AvKARE listed several definitions of "manufacturer" found in various statutes and agency regulations applicable to the pharmaceutical industry. See AR Tab 361.

Despite its assertion about its status as a manufacturer, however, AvKARE also defended its inclusion of the letter of supply from itself to itself, representing that the letter was "the very same letter that has been provided for 5 years for Modifications and has been accepted by the VA NAC under this very same procurement" and that "AvKARE is the only source of supply that can provide letters of commitment for [its products]." Id. at 21672.

AvKARE also took issue with the CO's determination that it lacked significant sales to the general public, stating that it "disagree[d] entirely" with the VA's characterization of its sales to federal end users via wholesalers as "indirect" sales to the government. See id. at 21677. AvKARE posited that "the VA does not have the discretion to disregard millions of dollars of commercial sales as 'insignificant,'" and that, in any event, "there is no requirement for any commercial sales in order to be eligible for an FSS contract." Id. at 21678.

Lastly, AvKARE reiterated its belief that it did not need to comply with the CSP requirements applicable to dealer/resellers because "we are not a dealer or reseller." Id. at 21679. Instead, AvKARE contended, "[w]e are distributing and selling AvKARE's finished end product" and "[the dealer/reseller] provision is not applicable to our offer." Id.

VIII. VA Warns AvKARE that its Renewal Offer Remains Unacceptable

On February 12, 2015, the CO informed AvKARE by letter that its renewal offer "remain[ed] unacceptable" because of "several deficiencies" in its response. AR Tab 367 at 21695. The CO made clear that the VA "does not consider AvKARE to be a manufacturer" and stated that the definitions of "manufacturer" that AvKARE attached to its response were "not applicable" to the solicitation. Id. at 21696. After reminding AvKARE that "[the] CO is required to make a determination that . . . prices are fair and reasonable before an award can be made," the CO provided AvKARE with a new "Missing Information Open Item Spreadsheet," warning that "[a]bsent a current, complete, and accurate response . . . no further action w[ould] be taken" and AvKARE's offer would be returned. Id.

AvKARE responded to the VA's letter on February 18, 2015. AR Tab 370. It explained that while "[n]o production operations take place" at the location it had listed

on its offer, it had "entered into a production and quality control agreement" with a different company under which that company "serves as the contract manufacturer for AvKARE." Id. at 21706. AvKARE also wished to "put[] aside the manufacturer vs non-manufacturer debate" and suggested that the CO could use multiple techniques to assess price reasonableness rather than solely relying on manufacturers' CSP information. Id. at 21705–06.

Shortly afterwards, the CO again followed up with AvKARE. AR Tab 372. He clarified the VA's position that AvKARE's letter of supply did not "satisfy the requirements" applicable to a "contractor who is other than the manufacturer" set forth in Clause I-FSS-644. Id. at 21712. Further, he explained that "[t]he [CO] is given wide latitude when determining if commercial sales are insignificant." Id. at 21713–14. Finally, he explained that while AvKARE was "welcome to provide market research and other pricing information to supplement the requisite CSP information," the CSP information was still required. Id. at 21714.

IX. AvKARE's First Bid Protest and the VA's Extension of the Existing Contact

After receiving the CO's letter reiterating the VA's demand for manufacturers' CSP data, AvKARE filed a bid protest action in this Court. See Compl., AvKARE, Inc. v. United States (AvKARE I), No. 15-cv-216, ECF No. 1 (March 3, 2015). The next day, AvKARE sent additional responses to the CO. AR Tab 380. Once again, AvKARE reaffirmed its self-designation as a "manufacturer," stating that it "directs all faucets [sic] of the production side of the product" in the same manner as "many companies within the pharmaceutical industry." Id. at 21732. At the same time, though, AvKARE agreed to provide copies of its agreements with its "bulk medication suppliers," which it believed would "satisfy the requirement [of Clause I-FSS-644] as evidence that AvKARE will have the component supplied for the contract period." Id. at 21733. In terms of updating its CSP information, AvKARE attached newly-received "sales tracings" from its wholesalers, which it claimed "should prove that any wholesaler should be considered a commercial customer based on the fact they are selling these products to their OWN customer base." Id. at 21734–35 (emphasis in original).

After AvKARE filed its first bid protest, the government agreed to extend AvKARE's contract through September 31, 2015, and AvKARE voluntarily dismissed that case. See Notice of Voluntary Dismissal, AvKARE I, ECF No. 17. To move the renewal process forward, AvKARE indicated it would "submit[] requests to its suppliers to ascertain their willingness to supply their CSP information," even though AvKARE continued to believe that:

> [T]his information is neither required (as AvKARE is the manufacturer of its private label products and has significant commercial sales of those products) nor relevant (we fail to see how the prices paid for bulk pharmaceuticals is useful for assessing price reasonableness for a different deliverable – individually packaged and labelled bottles . . . of product).

AR Tab 382 at 21740. In addition, AvKARE "urge[d] the VA to formally state whether it [was] requiring AvKARE's competitors to submit supplier CSP information as a pre-requisite for either renewing their contracts or approving RFMs to add products to their contracts." Id. If not, AvKARE hoped that "we can agree that imposing such a requirement on AvKARE is not appropriate." Id.

X. VA Concludes AvKARE Lacks Significant Commercial Sales and Declines to Proceed Without Manufacturers' CSP Information

On April 1, 2015, the CO updated AvKARE on its deliberations, reiterating that the VA's position on AvKARE's status as a dealer/reseller "has not changed." AR Tab 386 at 22315. Moreover, the CO asserted that "we do not and cannot adapt a different or varied definition and/or version of manufacturer to individually suit a vendor" and that "any offer submitted by any company with the current deficiencies identified in AvKare's offer[] would have been no-awarded." Id. at 22316. The next day, the CO sent AvKARE explaining that the VA "require[d] assistance from [OIG] in the analysis of [AvKARE's sales] data to identify those sales that can be attributed to commercial customers." AR Tab 387 at 22318. Once that analysis was complete, the CO would "then consider whether CSP data will be required from the manufacturers." Id.

The OIG completed its review August 26, 2015. AR Tab 191. At bottom, it determined that AvKARE had "insufficient commercial sales from which to determine fair and reasonable pricing." Id. at 21069. In the OIG's view, AvKARE's sales to wholesalers were "indirect sales" rather than "commercial sales" because "all units sold to wholesalers were in turn sold to AvKARE's customers" instead of on the open market. Id. at 21070–72. Further, of these indirect sales, "only 0.51 percent were sold to customers classified as commercial in AvKARE's accounting system"—a percentage that was "not deemed significant."[9] Id. at 21072.

After receiving the OIG's report, the CO informed AvKARE by letter on September 3, 2015, that she had "reviewed all pertinent information" and "determined that AvKARE does not have sufficient commercial sales to make a fair and reasonable price determination." AR Tab 417 at 22496. Therefore, "[i]n order to proceed with evaluation of your offer, you must provide manufacturer CSP data." Id.

XI. This Action

On September 11, 2015, AvKARE filed its complaint in this Court, along with a motion for a preliminary injunction. ECF Nos. 1, 5. Following a status conference, the government agreed to extend AvKARE's existing contract through January 31, 2016, and

[9] In addition, the OIG noted that the prices in AvKARE's commercial price list would be revised effective as of the date the VA approved AvKARE's renewal offer. AR Tab 191 at 21072. According to the OIG, "[c]ommercial entities, who sell primarily to commercial customers, would never have a catalog price that is dependent upon an awarded FSS contract." Id.

the Court denied AvKARE's preliminary injunction motion as moot. See Order, ECF No. 11. The government compiled the administrative record, which AvKARE then moved to supplement. ECF No. 21. After hearing oral argument, the Court denied AvKARE's motion in its entirety. See Opinion and Order, ECF No. 32.

The parties then filed cross-motions for judgment on the administrative record. ECF Nos. 28, 37. The Court held oral argument on the cross-motions on January 13, 2016, after which the government agreed to further extend AvKARE's existing contract through the end of February. On January 28, AvKARE filed a second motion to supplement the administrative record. These motions are now ripe for decision.

DISCUSSION

I. Jurisdiction

A. The Court of Federal Claims' Bid Protest Jurisdiction

The Court of Federal Claims' bid protest jurisdiction is defined by 28 U.S.C. § 1491(b)(1). That provision grants the court jurisdiction to "render judgment on an action by an interested party objecting to . . . a proposed award or the award of a contract or any alleged violation of statute or regulation in connection with a procurement or a proposed procurement."

In keeping with this statutory grant, only an "interested party" has standing to invoke the Court of Federal Claims' bid protest jurisdiction. CGI Fed. Inc. v. United States, 779 F.3d 1346, 1348 (Fed. Cir. 2015); Myers Investigative and Sec. Servs., Inc. v. United States, 275 F.3d 1366, 1369 (Fed. Cir. 2002). As the Federal Circuit has explained, an "interested party" is "an actual or prospective bidder . . . whose direct economic interest would be affected by the award of the contract." CGI Fed., 779 F.3d at 1348 (quoting Am. Fed'n of Gov't Employees, AFL-CIO v. United States, 258 F.3d 1294, 1299 (Fed. Cir. 2001); see also Info. Tech. & Applications Corp. v. United States, 316 F.3d 1312, 1319 (Fed. Cir. 2003).

In a pre-award protest challenging an agency's evaluation of a proposal, a plaintiff has a direct economic interest if it has a "substantial chance" of winning the contract but for the alleged error in the evaluation. Orion Tech., Inc. v. United States, 704 F.3d 1344, 1348–49 (Fed. Cir. 2013); see also Tinton Falls Lodging Realty, LLC v. United States, 800 F.3d 1353, 1358 (Fed. Cir. 2015); Bannum, Inc. v. United States, 404 F.3d 1346, 1358 (Fed. Cir. 2005). That is, the protestor's chance of securing the award "must not [be] insubstantial." Info. Tech., 316 F.3d at 1319. Put differently, the protester must have been "prejudiced" by the alleged error. Tinton Falls, 800 F.3d at 1358.

B. The Court of Federal Claims' Jurisdiction Over Contract Claims

This Court's jurisdiction over contract claims is set forth in 28 U.S.C. § 1491(a). That provision grants the court jurisdiction over claims "founded . . . upon . . . any express or implied contract with the United States," including "any claim by or against, or dispute with, a contractor arising under [the Contract Disputes Act], including a

dispute concerning termination of a contract, rights in tangible or intangible property, compliance with cost accounting standards, and other nonmonetary disputes on which a decision of the contracting officer has been issued under . . . that Act." Id. § 1491(a)(1)–(2).

Claims "arising under" the CDA include claims based on "any express or implied contract . . . made by an executive agency for . . . the procurement of property, other than real property in being." 41 U.S.C. § 7102(a). Under the CDA, "procurement" means "the acquisition by purchase, lease or barter, of property or services for the direct benefit or use of the Federal Government." New Era Constr. v. United States, 890 F.2d 1152, 1157 (Fed. Cir. 1989) (quotation and emphasis omitted). Importantly, a contractor may not bring an action governed by the CDA in federal court before the "receipt of a contracting officer's decision" on its claim. 41 U.S.C. § 7104(b)(3); see M. Maropakis Carpentry, Inc. v. United States, 609 F.3d 1323, 1327–28 (Fed. Cir. 2010). Thus, the Court of Federal Claims does not possess jurisdiction over claims arising under the CDA unless the contractor has submitted a valid claim to the contracting officer and received the contracting officer's final decision on that claim. M. Maropakis Carpentry, 609 F.3d at 1327–28; see also Dalton v. Sherwood Van Lines, Inc. v. United States, 50 F.3d 1014, 1017 (Fed. Cir. 1995) ("When the Contract Disputes Act applies, it provides the exclusive mechanism for dispute resolution; the Contract Disputes Act was not designed to serve as an alternative administrative remedy, available at the contractor's option.").

The definition of "claim" for purposes of the CDA derives from the Federal Acquisition Regulations (FAR). See M. Maropakis Carpentry, 609 F.3d at 1327–28. As pertinent here, FAR 2.101 defines "claim" as "a written demand or written assertion by one of the contracting parties seeking, as a matter of right, the payment of money in a sum certain, the adjustment or interpretation of contract terms, or other relief arising under or relating to the contract." Id.; see also FAR 52.233-1 (setting forth, in a standard contract clause, the same definition of "claim" as in FAR 2.101).

C. Application of Jurisdictional Provisions to AvKARE's Claims in this Case

AvKARE's first claim is that the VA misinterpreted and misapplied the solicitation's CSP provision when it characterized AvKARE as a "dealer/reseller" rather than a "manufacturer," and, as a consequence, refused to further evaluate its renewal offer unless it provided its suppliers' CSP information. AvKARE further contends that the VA was motivated by animus toward AvKARE when it demanded this CSP information, and that it did so in bad faith to prevent AvKARE from obtaining a new contract.

These claims fall within the Court's bid protest jurisdiction under section 1491(b)(1) because they concern alleged errors or violations of law in the evaluation of AvKARE's proposal. Further, AvKARE has standing as an "interested party" to press its challenges to the VA's actions. It is an incumbent contractor, it submitted an actual offer, and it has alleged that its offered prices are lower than the prices for similar items already on the schedule. Thus, AvKARE has a substantial chance

of securing the contract if its offer in fact conforms to the solicitation's requirements. Accordingly, the Court has jurisdiction over AvKARE's first claim.

AvKARE's second claim relates to the VA's refusal to grant RFMs on its existing contract. AvKARE contends that this refusal was based on a misinterpretation of the contract and applicable regulations, and on the VA's animus toward AvKARE. The government argues that the Court lacks jurisdiction over AvKARE's RFM claims because those claims are subject to the CDA and AvKARE has not submitted "claims" within the meaning of the CDA to the CO. Def.'s Cross-Mot. for J. on the Admin. R. (Def.'s Cross-Mot) at 25, EFC No. 37; Def.'s Reply at 1–4, ECF No. 40. AvKARE disagrees. In its view, its RFM claims properly fall under the Court's bid protest jurisdiction, rather than its contract jurisdiction, because "the RFM process is akin to a new offer for [an] award of items within the scope of the FSS solicitation." Pl.'s Reply at 5–6, ECF No. 38.

AvKARE's position lacks merit. The Federal Circuit has made clear that contract modifications within the scope of an existing contract do not constitute "procurements" under section 1491(b)(1). See Distrib. Sols., Inc. v. United States, 539 F.3d 1340, 1346 (Fed. Cir. 2008); see also AT&T Comms., Inc. v. Wiltel, Inc., 1 F.3d 1201, 1204–05 (Fed. Cir. 1993). AvKARE's RFMs were clearly within the scope of the contract; indeed (as discussed above) the solicitation includes a contract modification provision, which AvKARE followed in submitting its RFMs. And the CDA's broad definition of "claim" clearly encompasses non-monetary relief of the type AvKARE seeks. See FAR 2.101 (defining "claim" to include "a written demand . . . seeking . . . the payment of money in a sum certain, the adjustment or interpretation of contract terms, or other relief arising under or relating to the contract") (emphasis added). It follows that AvKARE's claims related to its RFMs are governed by section 1491(a) and, by extension, the CDA. Accordingly, because AvKARE has not alleged that it submitted claims under the CDA to the CO or received any final determinations, the Court lacks jurisdiction over AvKARE's RFM-related claims in this case.

II. The Merits of AvKARE's Bid Protest

A. The Meaning of "Manufacturer" Under the Solicitation's CSP Provision

1. The Text of the Provision

The primary issue raised by AvKARE's bid protest claim is a legal one: whether AvKARE is a "manufacturer" or is instead a "dealer/reseller" within the meaning of the CSP clause, which was included in the solicitation pursuant to the requirements of the GSA regulation codified at 48 C.F.R § 515.408. The Court begins its analysis by reviewing the "plain meaning" of the regulatory language. Lengerich v. Dep't of Interior, 454 F.3d 1367, 1370 (Fed. Cir. 2013) ("We construe a regulation . . . by ascertaining its plain meaning." (citing Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414–15 (1945))); Lockheed Corp. v. Widnall, 113 F.3d 1225, 1227 (Fed. Cir. 1997) ("To interpret a regulation we must look at its plain language and consider the terms in

accordance with their common meaning."); see also Chase Bank USA, N.A. v. McCoy, 562 U.S. 195, 204 (2011) (analysis of regulation's meaning begins with its text).

The dictionary definition of the word "manufacture" is "[t]o make or process (a raw material) into a finished product."[10] Am. Heritage Dict. of the English Language 1067 (4th ed. 2000). By contrast, a "dealer" is "[o]ne that is engaged in buying and selling," id. at 467; and a "reseller" is one who "sell[s] again," id. at 1483.

Guidance that the VA has provided to prospective offerors on its website is consistent with the dictionary definition of "reseller." Information for Resellers, U.S. Dep't of Veterans Affairs, http://www.va.gov/oal/business/fss/resellers.asp (last visited February 11, 2016). It defines a "reseller" as "a company or individual that purchases commercial goods or services with the intention of reselling them rather than consuming or using them." Id.

In this case, the products that federal agencies purchase through the FSS are pills and other pharmaceuticals. And it is AvKARE's suppliers, not AvKARE, that assemble the raw materials needed to make the pills and other pharmaceuticals into finished products for the consumption of patients in VA and other government medical facilities. AvKARE's suppliers, therefore, clearly fall within the plain meaning of the term "manufacturer" as set forth above.

AvKARE, by contrast, purchases the pills and pharmaceuticals from the manufacturers in bulk with the intent to resell them to buyers through the FSS. It thus falls under the dictionary definition of "reseller." To be sure, AvKARE repackages the pills in order to resell them under its own label. Nonetheless, it is the pills and other pharmaceuticals that the schedule's users are buying, not their packaging. AvKARE, accordingly is a "dealer/reseller" of the pills and pharmaceuticals. It is not their manufacturer.

The Court notes that this common sense construction of the regulatory terms is also consistent with the way that the term "manufacturer" is used elsewhere in the solicitation. For example, the solicitation's "Offeror Representations and Certification" section defines "place of manufacture" as "the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government." AR Tab 2 at 86. In this context, the act of "process[ing] from raw materials" most readily describes the functions of a pill-maker, rather than a repackager.

Similarly, Clause I-FSS-644 of the solicitation requires any offeror "if other than the manufacturer" to submit assurances from its suppliers confirming the offeror's ability

[10] The Federal Circuit has observed that a court "may consult dictionaries" to determine the "ordinary, established meaning" of a word or phrase. Hymas v. United States, No 2014-5150, 2016 WL 158470, at *6 (Fed. Cir. Jan. 14, 2016) (quoting Info. Tech., 316 F.3d at 1320).

to meet the government's purchasing needs. See AR Tab 4 at 181. Offerors who are manufacturers are not required to provide such additional "assurances" because they themselves have control over the production of the pills. On the other hand, an entity like AvKARE, which does not make the pills, but merely repackages them, is most logically characterized as "other than a manufacturer" for purposes of this provision because it must rely on its suppliers to enable it to satisfy the purchasers' needs for pharmaceutical products.[11]

AvKARE argues, nonetheless, that it should be considered a manufacturer because the products it is offering to provide on the FSS are not simply pills, but pills that are properly packaged and labelled, and assigned a unique National Drug Code (NDC) that belongs exclusively to AvKARE. Pl.'s Mem. at 25–26; Pl.'s Reply at 10; see also Compl. ¶ 28. According to AvKARE, it is the only entity that can claim to be the "manufacturer" of the products sold under its labels.

Contrary to AvKARE's contentions, however, unique NDCs are assigned to any entity engaged in the "manufacturing or processing" of drugs, including any entity that "repackage[es] or otherwise chang[es] the container, wrapper, or labeling of any drug package to further the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer." 21 C.F.R. § 207.3(a)(8); see also id. §§ 207.20, 207.35. The assignment of a unique NDC to AvKARE does not, therefore, reveal anything one way or the other about whether it is the "manufacturer" of the products it wishes to offer either for purposes of the GSA regulation or for purposes of the statute and regulations governing the assignment of NDCs.

Accordingly, because pills and other pharmaceuticals are the relevant products, only a pill or pharmaceutical maker fits the plain meaning of "manufacturer" as used in the solicitation. And because AvKARE does not make pills or other pharmaceuticals, but rather buys them in bulk and sells them after repackaging them, it is not a manufacturer under the solicitation, but rather a dealer/reseller.

[11] As described above, notwithstanding its insistence that it is a "manufacturer," AvKARE's renewal proposal included what it characterizes as a letter of supply in response to Clause I-FSS-644. AR Tab 18 at 585. In the letter (as described above), the President of "AvKARE, Inc." purported to provide assurances to the contracting officer at "AvKARE" that AvKARE Inc. would ensure a sufficient quantity of pharmaceutical products to meet the needs of government purchasers. Of course, because AvKARE was, in fact, not the manufacturer of the pills, its promise to itself to ensure an adequate supply of the product could hardly serve as the type of assurance that Clause I-FSS-644 contemplates. For that reason, the VA required AvKARE to go back and get letters from the manufacturers who sell their pills and other pharmaceuticals to AvKARE.

2. Definitions of "Manufacturer" Found in Other Statutory and Regulatory Regimes that Apply to the Pharmaceutical Industry

Notwithstanding the plain meaning of the regulatory language, AvKARE emphasizes that repackagers like itself are considered "manufacturers" under other statutory and regulatory regimes that apply to the pharmaceutical industry. See Pl.'s Mem. at 24–27; Pl.'s Reply at 7–11. Therefore, it contends, the VA's conclusion that AvKARE is not a "manufacturer" for purposes of the GSA regulations was necessarily incorrect.

GSA has not provided any guidance concerning the interpretation of the terms "manufacturer" or "dealer/reseller." But it is worth remembering that the GSA regulation distinguishing between "manufacturers" and "dealer/resellers" governs with respect to all products sold on the FSS. It seems incongruous, therefore, to apply to the GSA regulations an industry-specific understanding of the term "manufacturer," particularly one drawn from other regulatory regimes.

In the Court's view, the meanings ascribed to the term "manufacturer" in the statutory and regulatory regimes that AvKARE cites are not relevant to the interpretation and application of the term "manufacturer" as it appears in the GSA regulation. To the contrary, the import of the cited statutes and regulations is that when legislators and regulators wish to subject entities like AvKARE that repackage and re-label pharmaceuticals to the same restrictions as entities that fall within the plain meaning of the term "manufacturer" set forth above, they do so explicitly.

For instance, AvKARE cites 38 U.S.C. § 8126. Pl.'s Mem. at 27. That statute requires all "manufacturers" of covered drugs to enter agreements with the Secretary of the VA to make those drugs available for procurement on the FSS at capped prices. The drugs subject to the requirement are single-source drugs—i.e., drugs that remain under patent protection. See 38 U.S.C. § 8126(a). For purposes of section 8126, Congress specified that the term "manufacturer" would include not only those entities that most naturally fall within the plain meaning of that term (such as those engaged in "the production, preparation, propagation, compounding, conversion, or processing of prescription drug products"), but also those entities engaged "in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products." 38 U.S.C. § 8126(h)(4).

The fact that Congress found it necessary to explicitly define the term "manufacturer" to include repackagers, relabelers, and distributors in section 8126(h)(4) suggests to the Court that such entities would not otherwise be considered "manufacturers" of drug products in light of that term's ordinary meaning. Further, there are unique policies underlying section 8126(h)(4) that justify including entities other than the pharmaceutical makers themselves within the definition of "manufacturer." By defining "manufacturer" to include repackagers in section 8126, Congress advanced the statute's underlying policies by ensuring that the government would have an adequate supply of the covered drugs at capped prices regardless of whether the pharmaceuticals

are purchased directly from their makers or from other entities like AvKARE that repackage and relabel them.

Similarly, when statutes and regulations enforced by the FDA make repackagers subject to the same rules as pill manufacturers, they do so by explicitly defining "manufacture" or "manufacturer" to include repackagers. See, e.g., 21 U.S.C. § 802(15) (specifying that, for purposes of the Controlled Substances Act, "[t]he term 'manufacture' means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly . . . and includes any packaging or repackaging of such substance or labeling or relabeling of its container"); 21 U.S.C. § 360 (specifying that, for purposes of the FDA's registration requirements, "the term 'manufacture, preparation, propagation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device").

As was the case with the expanded definition of "manufacturer" contained in section 8126(h)(4), there are specific policy reasons underlying these statutes and regulations that justify extending the restrictions that apply to manufacturers to entities like AvKARE that repackage and relabel drugs. For example, the Controlled Substances Act is designed to, among other things, avoid the diversion of certain pharmaceutical products to illegal markets. See 21 U.S.C. § 823. In that context, it requires the "manufacturers" of such products to register with the Attorney General, and defines manufacturer broadly to include entities like AvKARE that are also in the chain of distribution. Id. Similarly, under 21 U.S.C. § 360, AvKARE is subject to registration requirements that are part of a statutory and regulatory scheme intended to prevent the adulteration or misbranding of drugs; in that context, there exists a policy reason for subjecting repackagers and relabelers to the same restrictions as manufacturers.

Further, as AvKARE acknowledges, other FDA regulations define manufacturer more narrowly. See 21 C.F.R. § 201.1(b) (defining "manufacturer" for purposes of certain FDA labeling requirements as "the person who performs all of the following operations that are required to produce the product: (1) Mixing, (2) granulating, (3) milling, (4) molding, (5) lyophilizing, (6) tableting, (7) encapsulating, (8) coating, (9) sterilizing, and (10) filling sterile, aerosol, or gaseous drugs into dispensing containers"); Pl.'s Mem. at 25 n.8. This variance shows that even within the regulatory regime applicable to the pharmaceutical industry, the term "manufacturer" does not always include repackagers like AvKARE.

In short, the Court is not persuaded by AvKARE's reliance upon other statutory and regulatory applications of the term "manufacturer." For that reason, and the others discussed above, the Court holds that AvKARE is not a manufacturer under the solicitation's CSP provision; it is a dealer/reseller.

B. The CO's Determination that AvKARE Lacked Significant Commercial Sales

Under the solicitation, a dealer/reseller like AvKARE must produce manufacturers' CSP information only if it also lacks significant commercial sales. See AR Tab 5 at 202; id. Tab 12 at 503. And, as the solicitation makes clear, whether a dealer/reseller has significant commercial sales is "examined on a case by case basis." Id. Tab 12 at 503.

It is axiomatic that the Court will not interfere with an agency's procurement decision unless the decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." E.g., Bannum, Inc., 404 F.3d at 1351 (citing 5 U.S.C. § 706(2)(A)). Under this "highly deferential" standard, Advanced Data Concepts, Inc. v. United States, 216 F.3d 1054, 1058 (Fed. Cir. 2000) (citing Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 285 (1974)), the Court will not disturb the agency's decision unless it "lacked a rational basis" or "involved a violation of regulation or procedure," Impresa Construzioni Geom. Domenico Garufi v. United States, 238 F.3d 1324, 1332–33 (Fed. Cir. 2001). The plaintiff thus "bears a heavy burden" in attempting to show that a procuring agency's decision lacked a rational basis. Id. (quoting Saratoga Dev. Corp. v. United States, 21 F.3d 445, 456 (D.C. Cir. 1994)). Indeed, such a challenge may succeed only if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or [if] the decision is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Ala. Aircraft Indus., Inc.–Birmingham v. United States, 586 F.3d 1372, 1375 (Fed. Cir. 2009) (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983) (internal quotations omitted).

Here, in determining that AvKARE lacked significant commercial sales, the CO relied on an analysis conducted by the OIG. See AR Tab 191 at 21070–73; AR Tab 417 at 22496. The OIG assessed AvKARE's sales data and determined that nearly all of AvKARE's sales were indirect sales to government entities via commercial wholesalers. AR Tab 191 at 20170–71. The OIG also explained why it did not consider these sales to be commercial sales. Id. at 21070. The CO's reliance on the OIG's analysis thus was not unreasonable. Therefore, the CO's ultimate determination that AvKARE lacked significant commercial sales also had a rational basis.

AvKARE challenges the CO's decision on several other grounds, but these attacks also fail. Its first argument—that the VA refuses to award contracts to any offeror without significant commercial sales—knocks down a straw man, for the VA has not taken that position. See Pl.'s Mem. at 29; Pl.'s Reply at 15–16. Rather, the VA requires that dealer/resellers without significant commercial sales provide manufacturers' CSP information before conducting a price reasonableness analysis, after which it may award a contract.

AvKARE next argues that it "possesses significant commercial sales by virtue of the $9 million in such sales disclosed in its renewal offer." Pl.'s Mem. 30. But despite

this bald assertion, AvKARE offers no basis to question the OIG's analysis of these sales, which ultimately determined that the $9 million in sales did not, in fact, constitute significant commercial sales. Finally (and as discussed in more detail below), AvKARE contends that by relying on the OIG's analysis, the CO abdicated her responsibility to apply independent judgment. Pl.'s Mem. at 38; Pl.'s Reply at 15 n.6, 18–19. But because AvKARE has offered no concrete reason to question the OIG's analysis, it is difficult for the Court to discern how the CO's reliance on it could be cause for concern; and the record does not otherwise bear out this accusation.

Accordingly, the Court concludes that the CO's determination that AvKARE lacked significant commercial sales was not arbitrary, capricious, or contrary to law.

C. AvKARE's Claim that the VA Acted in Bad Faith

More broadly, AvKARE contends that the VA failed to evaluate its renewal offer and conduct negotiations in good faith. See Pl.'s Mem. At 38–39; Pl.'s Reply at 19. In AvKARE's view, the OIG developed "animus" toward AvKARE, and the CO then colluded with the OIG in rejecting AvKARE's proposal, thereby abdicating her responsibility to apply independent judgment. Pl.'s Mem. at 38; Pl.'s Reply at 19.

Agency decisionmaking, however, is entitled to the presumption of regularity. See Info. Tech., 316 F.3d at 1323 n.2. And the record here offers no basis for finding that presumption rebutted. Instead, it shows that the VA communicated regularly with AvKARE about AvKARE's proposal, and that the VA repeatedly explained to AvKARE why the proposal remained deficient. See AR Tab 344 at 21600–10; AR Tab 367 at 21695–97; AR Tab 386 at 22315–17. Moreover, the VA's internal communications exhibit no predisposition to spurn AvKARE's offer; rather, they reflect a consistent position that AvKARE's proposal was not complete because AvKARE was not a manufacturer, lacked significant commercial sales, and had not supplied manufacturers' CSP information. See AR Tab 174 at 20957; AR Tab 188 at 21059–61; AR Tab 191 at 21069, 21073; AR Tab 436 at 22534.

AvKARE also appears to assert that the government acted in bad faith by declining to use an alternate method of price analysis—i.e., one that did not depend on securing and reviewing its suppliers' CSP information. See Pl.'s Reply at 16 & n.7. At oral argument, for example, AvKARE claimed that the VA should have employed alternative methods because the pill suppliers (i.e., the manufacturers) do not sell what AvKARE sells (i.e., pills packaged in bottles for individual consumption) so that there was no relevant manufacturers' CSP information to be obtained from AvKARE suppliers. Tr. of Oral Arg. at 10:10–11:11, ECF No. 42.

Counsel for the government was not able to specify at oral argument the precise nature of the manufacturers' CSP information that the VA is seeking. Id. at 48:6–51:16. But it is certainly conceivable that the VA may wish to consider, for example, information about the prices AvKARE's suppliers charge repackagers or other entities for pills purchased in bulk that will ultimately be sold to the general public.

In any event, it is premature on the present record to address AvKARE's apparent contention that the VA has no use for any CSP information that AvKARE might be able to secure from its suppliers. The government has confirmed that if relevant manufacturers' CSP information was demonstrably unobtainable by AvKARE, through no fault of its own, then the VA was willing (and, the Court assumes, remains willing) to employ a different method of price analysis to evaluate AvKARE's proposal. See Def's Opp'n to Pl.'s 2d Mot. to Suppl. the Admin. R. at 4, ECF No. 45.[12]

But AvKARE made no attempt before the VA to substantiate the position it is taking before the Court that relevant information about its suppliers' commercial sales practices cannot be obtained. Rather, it consistently took the position that it was not legally obligated to provide any such information at all, even if it did exist, because AVKARE is not a dealer/reseller and/or because its suppliers' commercial sales practices could not possibly be relevant to a determination of whether AvKARE's prices were fair and reasonable. See AR Tab 360 at 21679 (asserting that AvKARE need not provide manufacturers' CSP information because "we are not a dealer or reseller" and "[the dealer/reseller] provision is not applicable to our offer"); AR Tab 382 at 21740 (asserting AvKARE's belief that manufacturers' CSP information "is neither required (as AvKARE is the manufacturer of its private label products and has significant commercial sales of those products) nor relevant"). Thus, the record provides no basis to conclude that the VA has in bad faith requested information that it knows does not exist as AvKARE claims.[13]

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[12] Indeed, at least one document in the record contemplates just this outcome. See AR Tab 436 at 22534 (email from the VA's FSS director stating that "[i]f CSP data is not received, AvKare must prove that CSP data is not available from their manufacturers," and that "[if] CO verified CSP data is not available from manufacturer, then proceed to reliance solely on price analysis").

[13] AvKARE's second motion to supplement the administrative record relates to this portion of its claim. In it, AvKARE seeks to supplement the AR with a transcript of a deposition of the GSA's current director of FSS programs, which was taken in connection with a parallel proceeding before the Civilian Board of Contract Appeals. See Pl.'s Mem. in Supp. of its 2d Mot. to Suppl. the Admin. R. ("Pl.'s 2d Mot. to Suppl.") at 2–4, ECF No. 44. In the transcript, the director describes the GSA's policies and practices for obtaining CSP information and for assessing price reasonableness, and he recalls discussions he had about those policies and procedures with the VA's FSS program director. Id. at 4–9.

According to AvKARE, this testimony shows that the GSA told the VA that CSP information was "not an absolute necessity" and "could [not] be required when [it] w[as] not available from downstream suppliers." Id. at 12. As discussed above, the existing record reflects that this is the VA's understanding. See AR Tab 436 at 22534 (email outlining how to handle AvKARE proposal if "verified CSP data is not available from

D. AvKARE's De Facto Debarment Claim

Finally, AvKARE claims that the VA's refusal to further evaluate its renewal proposal amounts to a de facto debarment without due process of law. A de facto debarment occurs when there is "a systematic effort by the procuring agency to reject all of the bidder's contract bids." TLT Const. Corp. v. United States, 50 Fed. Cl. 212, 215–16 (2001) (quoting Stapp Towing, Inc. v. United States, 34 Fed. Cl. 300, 312 (1995)). To establish a de facto debarment, a contractor must show that the agency has either stated or engaged in conduct demonstrating that it will not award the contractor future contracts. Id. (citing CRC Marine Serv., Inc. v. United States, 41 Fed. Cl. 66, 84 (1998)).

AvKARE's de facto debarment claim fails for largely the same reasons as its bad faith treatment claim—namely, that the record reflects no systematic intent to refuse to award AvKARE future contracts. In fact, just the opposite is true: documents in the record show that the VA has consistently told AvKARE that it would move forward with reviewing AvKARE's proposal if AvKARE supplied the required manufacturers' CSP information. In contrapose, AvKARE has consistently maintained that the solicitation does not require it to provide the information the VA seeks. This disagreement about a legal issue is at the root of all of the controversies in this case, and its existence (without more) does not demonstrate any "systematic effort" to deny awards to AvKARE. See TLT Const. Corp., 50 Fed. Cl. at 215–16. Accordingly, AvKARE's de facto debarment claim must fail.

CONCLUSION

For the reasons discussed above, AvKARE's motion for judgment on the administrative record is **DENIED** and the government's motion is **GRANTED**. Accordingly, AvKARE's claims related to its RFMs are hereby **DISMISSED** without prejudice, and its bid protest claims are hereby **DISMISSED** with prejudice. AvKARE's second motion to supplement the administrative record is also hereby **DENIED**. The Clerk is directed to enter judgment accordingly. The parties shall bear their own costs.

[the] manufacturer[s]"). It also reflects that AvKARE has maintained that it is not legally obligated to provide the VA with manufacturers' CSP information, even if it does exist and is obtainable. The deposition testimony thus is not necessary to "permit meaningful review" in this case. See Axiom Res. Mgmt., Inc. v. United States, 564 F.3d 1374, 1380 (Fed. Cir. 2009). Accordingly, AvKARE's second motion to supplement the record is hereby **DENIED**.

IT IS SO ORDERED.

/s/ Elaine D. Kaplan
ELAINE D. KAPLAN
Judge