United States Small Business Administration
Office of Hearings and Appeals

SIZE APPEAL OF: Osang, LLC, Appellant, Appealed from Size Determination No. 06-2025-025	SBA No. SIZ-6358 Decided: June 11, 2025

APPEARANCES

Daniel H. Ramish, Esq., Jonathan D. Shaffer, Esq., Haynes and Boone, LLP, Vienna, Virginia, for Osang, LLC.

Shane J. McCall, Esq., Nicole D. Pottroff, Esq., John L. Holtz, Esq., Gregory P. Weber, Esq., Stephanie L. Ellis, Esq., Annie E. Birney, Esq., Koprince McCall Pottroff, LLC, Lawrence, Kansas, for Branch Medical LLC

DECISION[1]

I. Introduction and Jurisdiction

On March 18, 2025, the U.S. Small Business Administration (SBA), Office of Government Contracting — Area VI (Area Office) issued Size Determination No. 06-2025-025, concluding that Osang, LLC (Appellant) is not a small business for the subject procurement. On appeal, Appellant maintains that the size determination is clearly erroneous, and requests that SBA's Office of Hearings and Appeals (OHA) reverse. For the reasons discussed *infra*, the appeal is denied and the size determination is affirmed.

OHA decides size determination appeals under the Small Business Act of 1958, 15 U.S.C. § 631 *et seq.*, and 13 C.F.R. parts 121 and 134. Appellant filed the instant appeal within 15 days after receiving the size determination, so the appeal is timely. 13 C.F.R. § 134.304(a). Accordingly, this matter is properly before OHA for decision.

[1] This decision was originally issued under a protective order. After receiving and considering one or more timely requests for redactions, OHA now issues this redacted decision for public release.

II. Background

A. Solicitation

On September 10, 2024, the U.S. Department of Health and Human Services (HHS) issued Request for Proposals (RFP) No. 75A50424R00006, seeking a contractor to provide 1,000,000 multi-antigen diagnostic test kits. The Contracting Officer (CO) set aside the procurement entirely for small businesses, and assigned North American Industry Classification System (NAICS) code 325413, In-Vitro Diagnostic Substance Manufacturing, with a corresponding size standard of 1,250-employees. The RFP stipulated that "[t]he Government will only accept multi-antigen diagnostic tests from the original equipment manufacturer (OEM). No products offered from retailers, dealers, or authorized resellers will be accepted." (RFP at 5.)

The RFP set forth the full text of Federal Acquisition Regulation (FAR) clause 52.219-1 Small Business Program Representations (FEB 2024). (*Id.* at 39-43.) According to the clause, "[t]he small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce (*i.e.*, nonmanufacturer), is 500 employees." (*Id.* at 41.)

HHS initially selected Watmind USA Inc. for award, but that award was subsequently terminated. The CO then invited Appellant and other offerors to submit final proposal revisions, which were due November 19, 2024. (Letter from R. Roscoe (Nov. 14, 2024), at 1.)

B. Proposal

Appellant's proposal, dated November 19, 2024, included an "[a]uthorized distributor letter certified by the Original Equipment Manufacturer." (Proposal, Vol. III, at 2 and Appx. B.) The letter identified Osang Healthcare Co., Ltd. (OHC), a South Korea based company, as the "producer" and "exporter" of the test kits, and Appellant as the "importer." (Proposal, Vol. III, Appx. B.) The letter was signed by an OHC manager who attested to its accuracy. (*Id.*)

Appellant's proposal repeatedly named "Korea, Republic of" as the country of origin of the test kits. (Proposal, Vol. III at 10, 12.) Asked to specify whether the end items it would provide were manufactured predominantly inside or outside of the United States, Appellant marked the box "Outside the United States." (*Id.* at 14.)

C. Protest

On January 31, 2025, the CO announced that Appellant was the apparent awardee. On February 7, 2025, Branch Medical LLC (Branch), a disappointed offeror, filed a timely protest challenging Appellant's size.

In the protest, Branch alleged that Appellant is not a small business due to affiliation with its parent company, OHC, which is part of the larger Group Osang Co., Ltd. (Osang Group), based in South Korea. (Protest at 1.) The protest claimed that the combined size of Appellant and

its affiliates exceed the size standard. (*Id.* at 1-2.) The protest further questioned whether Appellant has a physical place of business in the United States, as required by 13 C.F.R. § 121.105(a)(1). (*Id.* at 6.) According to Branch:

> [Appellant] is not eligible for award for a multitude of reasons. First, [Appellant] lacks a proper place of business in the U.S. This is shown by the fact that its only stated physical locations appear to be "mail drops" from which no work is actually performed. [OHA] case law is clear that such a location is not an actual place of business. Further, [Appellant] is affiliated with OHC and Osang Group (along with Osang Group's other affiliates) under at least one, if not many, bases of affiliation. When these companies are combined, this should put [Appellant] over the size standard. In either case, [Appellant] is ineligible for award.

(*Id.* at 11.)

The CO forwarded Branch's protest to the Area Office for review. On March 3, 2025, Appellant responded to the protest. Appellant acknowledged affiliation with OHC, Osang Group, and 11 other concerns. (Protest Response at 2.) Nevertheless, Appellant maintained, Appellant and these affiliates together have only 828 employees, and Appellant therefore is still a small business under the 1,250-employee size standard applicable to this procurement. (*Id.* at 2-3.) Further, contrary to Branch's contentions, Appellant does have a regular place of business in the United States at 625 Fair Oaks Avenue, Pasadena, California. (*Id.* at 5-6.)

The Area Office requested that Appellant address its compliance with the nonmanufacturer rule, as set forth at 13 C.F.R. § 121.406 and FAR 19.505. In response, Appellant maintained that it meets most of the requirements of the rule. Appellant asserted that, for the subject procurement, it intends to supply test kits manufactured by a U.S.-based company, [Company A], which is a small business. (Letter from D. Ramish to E. Sanchez (Mar. 6, 2025), at 1, 3.) Additionally, Appellant's "primary business is serving as a retail and wholesale distributor of test kits," and Appellant will take ownership and possession of the test kits manufactured by [Company A]. (*Id.* at 3-4.) Appellant conceded that, together with its affiliates, Appellant has more than 500 employees. (*Id.* at 4.) This regulatory requirement, however, should not be enforced, because it is inconsistent with the statutory nonmanufacturer rule, 15 U.S.C. § 637(a)(17). The statute makes no mention of a 500-employee size standard, but rather indicates that a nonmanufacturer must "be a small business concern under the numerical size standard for the Standard Industrial Classification Code assigned to the contract solicitation on which the offer is being made." (*Id.* at 2-4, quoting 15 U.S.C. § 637(a)(17)(B)(ii).) In Appellant's view, "[t]he statute, by its terms, protects [Appellant's] eligibility as a nonmanufacturer because [Appellant] meets the size standard assigned to the solicitation, as well as the other parts of the statutory test." (*Id.* at 4.)

Appellant argued, alternatively, that it could be considered the manufacturer of the test kits, because Appellant "is merely an extension of its parent company," OHC, and OHC will manufacture the test kits in the event that Appellant "cannot supply the products of [Company A] in compliance with all applicable small business eligibility requirements." (*Id.* at 5.)

D. Size Determination

In March 18, 2025, the Area Office issued Size Determination No. 06-2025-025. The Area Office found that Appellant is small under the 1,250-employee size standard for NAICS code 325413. However, Appellant does not qualify under the nonmanufacturer rule for two reasons: (i) Appellant and its affiliates exceed the 500-employee threshold set forth at 13 C.F.R. § 121.406(b)(1)(i); and (ii) Appellant's proposal did not identify [Company A] or any other domestic small business manufacturer as the source of supply, and Appellant's post-award changes of approach cannot alter or substitute for the proposal. (*Id.* at 10-11.)

The Area Office noted that, under 13 C.F.R. § 121.406(a), in order to qualify as a small business concern for a small business set-aside for manufactured products, an offeror must either: (1) be the manufacturer or producer of the end item being procured (and the end item must be manufactured or produced in the United States); or (2) qualify as a nonmanufacturer. (*Id.* at 11.)

The Area Office found that Appellant is not the manufacturer of the test kits:

> [The Area Office] received and reviewed [Appellant's] proposal dated November 19, 2024. [Appellant] describes itself as a leader in in-vitro diagnostic technology and as an entity that was founded in 1996, therefore failing to distinguish [Appellant], which was founded in 2021, from its much older parent Company. A Certificate of Origin included in the proposal identifies the original equipment manufacturer as [OHC], [Appellant's] parent company in Korea. It also identifies [Appellant], with a location of 625 Fair Oaks Ave Ste 360, South Pasadena, as the importer of the procured articles. It appears to [the Area Office] that [Appellant] will serve as a dealer or an authorized reseller for its parent company. As is typical during a size determination process, [the Area Office] request[ed] clarification as to the party that would be producing the diagnostic test kits. In its response to questions from [the Area Office], [Appellant] asserts that the test kit units would be produced and assembled by a small business manufacturer in San Diego, California, and that [OHC] would only be used as a backup manufacturer. The small business manufacturer is unrelated and unaffiliated with [Appellant]. While [an area office] can accept post-proposal submittal clarifications during the course of a size determination process, [an area office] generally bases its size determination on information obtained from the proposal. In the case of [Appellant], regardless of whether the concern will be using its parent company or a San Diego-based manufacturer, it is clear that [Appellant] will not be manufacturing the items being procured.

(*Id.* at 9.)

The Area Office noted that the RFP specifically warned that "[n]o products offered from retailers, dealers, or authorized resellers will be accepted." (*Id.*, quoting RFP at 5.) Notwithstanding this instruction, "the solicitation adds confusion, as it also specifies that the nonmanufacturer rule [] applies to the instant RFP. The two requirements appear to be in direct

contradiction. Regardless, based on [the Area Office's] discussions with [Appellant], it is clear [] that [Appellant] would not meet the requirements as a manufacturer under 13 CFR § 121.406(a)(1). [The Area Office] therefore needs to validate compliance with the nonmanufacturer rule." (*Id.* at 9-10.)

The Area Office found that Appellant also does not qualify as a nonmanufacturer. More specifically, Appellant does not meet two of the four elements of the nonmanufacturer rule: (i) 13 C.F.R. § 121.406(b)(1)(i), which requires that to qualify as a small business nonmanufacturer, a concern must have 500 or fewer employees; and (ii) 13 C.F.R. § 121.406(b)(1)(iv), which requires that the end item must be manufactured by a small business located in the United States (unless a waiver has been granted). (*Id.* at 10-11.)

E. Appeal

On April 2, 2025, Appellant filed the instant appeal. Appellant contends that the Area Office improperly enforced the 500-employee cap for the nonmanufacturer rule set forth in SBA regulations and the FAR, rather than applying what Appellant argues is a broader eligibility framework established by 15 U.S.C. § 637(a)(17). (Appeal at 2-4.) More specifically, in Appellant's view, a firm qualifies as a manufacturer for small business purposes if it does not exceed the numerical size standard for the NAICS code assigned to the solicitation. Because Appellant, combined with its affiliates, falls within the 1,250-employee size standard for NAICS code 325413, Appellant contends that the 500-employee threshold imposed by regulation should not have been used to disqualify it. (*Id.*)

The Area Office [] erred by ruling that [Appellant] did not qualify as a nonmanufacturer because [Appellant] and its affiliates had more than 500 employees. The AO found that [Appellant] and its [affiliates] were small under the 1,250-employee size standard for NAICS Code 325413, but nevertheless found that the company did not qualify as a small business nonmanufacturer because [Appellant] and affiliates had more than 500 employees. [Appellant's] ability to perform this set-aside contract as a nonmanufacturer is conclusively established by statute. The Small Business Act provides a safe harbor for small business concerns that would otherwise be denied the opportunity to compete because they are nonmanufacturers if four requirements are met:

> (17) (A) An otherwise responsible business concern that is in compliance with the requirements of subparagraph (B) ***shall not be denied the opportunity to submit and have considered its offer for any procurement contract***, which contract has as its principal purpose the supply of a product . . . ***solely because such concern is other than the actual manufacturer*** or processor of the product to be supplied under the contract.
>
> *(B)* To be in compliance with the requirements referred to in subparagraph (A), such a business concern shall . . . (ii) ***be a small business concern under the numerical size standard for the Standard Industrial Classification Code assigned to the contract solicitation on which the offer is being made. . . .***

(*Id.* at 13, quoting 15 U.S.C. § 637)(a)(17) (emphasis added by Appellant) (internal citations omitted).)

Appellant renews its claim that it executed a manufacturing agreement with [Company A], a small business based in San Diego, prior to the date of its proposal. (*Id.* at 18.) Appellant contends that the contract with [Company A] prior to its proposal date satisfies the requirement under 15 U.S.C. § 637(a)(17)(B) to supply a domestically manufactured product. (*Id.* at 8-11.) Appellant further asserts that while [Company A] was not named in the proposal, the proposal alluded to Appellant's ability to manufacture the test kits domestically and that such language should suffice to satisfy the intent of the rule. (*Id.*)

Appellant insists that that 15 U.S.C. § 637(a)(17) provides an overriding statutory safe harbor that supersedes the regulatory cap of 500 employees for nonmanufacturers. According to Appellant:

> Congress did not leave any room for SBA to impose a lower employee size standard for nonmanufacturers than the size standard specified in the Solicitation. If a small business concern meets the test at 15 U.S.C. § 637(a)(17)(B), then it "shall not be denied the opportunity to submit and have considered its offer for any procurement contract," solely because it is not the manufacturer of the products being supplied under the contract. 15 U.S.C. § 637(a)(17)(A). The statute, by its terms, protects [Appellant's] eligibility as a nonmanufacturer because [Appellant] meets the size standard assigned to the solicitation, as well as the other parts of the statutory test.

(*Id.* at 16.)

Appellant concludes that because it fell below the 1,250-employee limit under NAICS code 325413, it was entitled to the benefit of the statute at 15 U.S.C. § 637(a)(17) and should not have been disqualified under the regulatory threshold. (*Id.*)

III. Discussion

A. Standard of Review

Appellant has the burden of proving, by a preponderance of the evidence, all elements of the appeal. Specifically, Appellant must prove the size determination is based upon a clear error of fact or law. 13 C.F.R. § 134.314. OHA will disturb an area office size determination only if, after reviewing the record, the administrative judge has a definite and firm conviction that the area office erred in making its key findings of fact or law. *Size Appeal of Taylor Consultants, Inc.*, SBA No. SIZ-4775, at 11 (2006.)

B. Analysis

The Area Office determined — and Appellant does not dispute — that Appellant does not qualify as a nonmanufacturer under the regulations at 13 C.F.R. § 121.406 and FAR 19.505. Sections II.D and II.E, *supra*. Instead, Appellant maintains that the Area Office erred in giving

effect to these regulations, because the Area Office should have found that Appellant meets the elements of the statutory nonmanufacturer rule, 15 U.S.C. § 637(a)(17), which supersedes any contrary regulations. Section II.E, *supra*. As discussed *infra*, though, the problem for Appellant is that Appellant makes no persuasive showing that it does, in fact, meet all elements of the statutory test. Rather, the record reflects that Appellant fails two of the four elements. As a result, this appeal is meritless and must be denied.

Under the statutory nonmanufacturer rule, a prime contractor "shall not be denied the opportunity to submit and have considered its offer for any procurement contract," provided that the prime contractor must:

> (i) be primarily engaged in the wholesale or retail trade;
>
> (ii) be a small business concern under the numerical size standard for the Standard Industrial Classification Code assigned to the contract solicitation on which the offer is being made;
>
> (iii) be a regular dealer . . . in the product to be offered the Government or be specifically exempted . . .; and
>
> (iv) represent that it will supply the product of a domestic small business manufacturer or processor, unless a waiver of such requirement is granted[.]

15 U.S.C. § 637(a)(17)(B).

Here, Appellant does not meet the second element of the statutory test, which requires that the prime contractor "be a small business concern under the numerical size standard for the Standard Industrial Classification Code assigned to the contract solicitation on which the offer is being made." Although Appellant emphasizes that it, together with its affiliates, does not exceed the 1,250-employee size standard associated with NAICS code 325413, Appellant overlooks that this was not the only size standard specified in the RFP. Rather, the RFP also set forth an alternative size standard for nonmanufacturers, stating that "[t]he small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce (*i.e.*, nonmanufacturer), is 500 employees." Section II.A, *supra*. The alternative 500-employee size standard for nonmanufacturers also is mandated by SBA regulations as broadly applicable to all procurements of supplies or manufactured products. 13 C.F.R. § 121.402(b)(2). Appellant concedes that it is not small under a 500-employee size standard. Section II.E, *supra*. Accordingly, given that a 500-employee size standard for nonmanufacturers was expressly included in the instant RFP, and given further that the relevant question presented here is compliance with the nonmanufacturer rule, Appellant has not shown that it is, in fact, "a small business concern under the numerical size standard . . . assigned to the contract solicitation."

Even if Appellant could establish that it meets the second element of the test, Appellant's compliance with the fourth element also appears dubious. As the Area Office recognized, Appellant's proposal stated that the test kits would be manufactured by OHC, Appellant's parent

company based in South Korea. Section II.B, *supra*. The proposal thus identified OHC as the "producer" and "exporter" of the test kits, and Appellant as the "importer." *Id.* Similarly, the proposal repeatedly named "Korea, Republic of" as the country of origin of the test kits. *Id.* In response to the protest, Appellant suggested that it could, instead, obtain the test kits from [Company A], a domestic small business. Section II.C, *supra*. A prime contractor's compliance with the nonmanufacturer rule, though, is assessed as of the date of final proposal revisions. 13 C.F.R. § 121.404(f). As a result, OHA thus has long held any changes of approach created in response to a protest may not be used to contradict the proposal. *Size Appeal of Mechanix Wear, LLC*, SBA No. SIZ-6098 (2021); *Size Appeal of BCI Constr. USA, Inc.*, SBA No. SIZ-6029 (2019); *Size Appeal of Coulson Aviation USA, Inc.*, SBA No. SIZ-5815, at 9-10 (2017) (a challenged firm cannot "re-write its Proposal in response to the protest"); *Size Appeal of Tech. Assocs., Inc.*, SBA No. SIZ-5814 (2017); *Size Appeal of Camp Noble, Inc. dba 3-D Mktg.*, SBA No. SIZ-5644 (2015); *Size Appeal of M1 Support Servs., LP*, SBA No. SIZ-5297 (2011); *Size Appeal of Fernandez Enters., LLC*, SBA No. SIZ-4863 (2007). Because Appellant's proposal made clear that Appellant would not supply the end products of a domestic small business manufacturer, Appellant has not shown that it meets the fourth element of the statutory test set forth at 15 U.S.C. § 637(a)(17)(B).

On appeal, Appellant also renews its claim that it could be considered the manufacturer of the test kits, because Appellant "is merely an extension of its parent company," OHC. Sections II.C and II.E, *supra*. This argument fails because SBA regulations provide that "[f]or size purposes, there can be only one manufacturer of the end item being acquired." 13 C.F.R. § 121.406(b)(2). Since Appellant's proposal indicates that OHC will manufacture the test kits, it follows that Appellant cannot also be the manufacturer.

IV. Conclusion

For the reasons above, the appeal is DENIED. By its own admission, Appellant does not meet the alternative 500-employee size standard as specified in the RFP for a nonmanufacturer, nor did Appellant propose to supply the end products of a domestic small business manufacturer. Even if OHA were to conclude, then, that the statutory nonmanufacturer rule at 15 U.S.C. § 637(a)(17) overrides and invalidates the regulations at 13 C.F.R. § 121.406 and FAR 19.505, the issue would be immaterial here, because Appellant has not shown that it meets the elements of the statutory nonmanufacturer rule. This is the final decision of the Small Business Administration. *See* 13 C.F.R. § 134.316(d).

KENNETH M. HYDE
Administrative Judge