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Non-TAA-Compliant Covered Drugs Must be Offered to the VA in the Coming Weeks

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Government Contracts

The United States Department of Veterans Affairs ("VA") recently announced a significant change in policy that will allow it to purchase drug products that were previously unavailable due to the Trade Agreements Act ("TAA") because they were manufactured in countries with whom the United States does not have a procurement agreement in place. The VA has issued a mass modification to its Federal Supply Schedule ("FSS") contracts for pharmaceutical products, Schedule 65 I B, requiring that contractors offer to the Government all single source and multiple source drug products (also referred to as SIN 42-2A products) that do not comply with the TAA (i.e., they are not U.S.-made or designated country end products). Despite its prior position, less than three years ago, that it would "*remove* all [SIN] 42-2A covered/branded drug products manufactured in a non-designated country . . . from all 65 I B Schedule contracts," the VA has decided that "[w]e *now accept* covered drugs that were formally excluded due to their 'TAA non-compliant' nature." Although this change in policy could represent significant opportunities for drug manufacturers to sell non-TAA-compliant drug products to the Government, the VA's anticipated timeline may present a cause for concern.

Under the TAA, contractors may only deliver U.S.-made or designated country end products, unless they identify that they intend to deliver non-TAA-compliant products and the Government makes a determination that an exception to the TAA applies. Relevant here, a TAA exception provides that the Government may purchase non-TAA-compliant products when it determines that there are no TAA-compliant products available. It appears that the VA intends for this non-availability exception to apply to all single source and innovator multiple source drug products manufactured outside the U.S. in non-TAA-designated countries, as these products are sufficiently unique to not have an adequate substitute and, by definition, cannot be offered from another source.

According to a recent website post from the VA's Office of Acquisition and Logistics, drug manufacturers must submit Non-Federal Average Manufacturer's Price ("NFAMP") calculations for covered drugs to the Office of Pharmacy Benefits Management Services by April 26, 2016. Current Schedule 65 I B contractors must then submit a request for modification by May 6, 2016, to add non-TAA-compliant products to their FSS contracts. This modification will include a "Trade Agreements Act Non-Availability Determination Request Letter" that lists the non-TAA-compliant covered drugs and requests that the Contracting Officer make the likely determination that the above-described non-availability exception applies. Drug manufacturers that do not currently hold a Schedule 65 I B contract (e.g., drug manufacturers that previously sold only non-TAA-compliant covered drug products) must also establish an Interim Agreement ("IA") with the VA in order to bridge the gap until a VA schedule contract is in place and make their products available as soon as possible. This IA will require drug manufacturers to enter a Master Agreement (outlining the contractor's responsibilities and obligations) and a

Pharmaceutical Pricing Agreement (containing the annual federal ceiling price ("FCP") for each covered drug, which constitutes the maximum price that may be charged to the Government). All non-TAA-compliant covered drug products must be on an FSS 65 I B contract or IA by June 6, 2016.

This accelerated timeline could present difficulties for some manufacturers, and presents several unanswered questions. For example, the VA has not articulated whether the agency will view a contractor's failure to meet the stated timeline as non-compliance with Veterans Health Care Act obligations, a determination that would have potentially serious consequences for the contractor. In addition, the stated timeline seems quite aggressive. Current schedule contract holders may have difficulty listing by June 6th if they have not been calculating NFAMP for non-TAA-compliant products, and even if they have, dual-pricers will likely have significant difficulties negotiating other government agency prices by that time. The execution of IAs may present similar issues in light of the short period allowed.

We will continue to monitor the VA's efforts to require contractors to list non-TAA-compliant covered drug products, but drug manufacturers should take note of these changes and quickly assess whether any of their products will require action under the new policy.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Government Contracts practice group:

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