Mission Pharmacal Company hereby submits this unclassified response with business proprietary information to the Request for Information (RFI) Number 75A50121C - "Domestic Public Health Industrial Base Capabilities and Capacities: Anti-Microbials," from the U.S. Department of Health and Human Services (HHS):

PART I – Required Business Information:

Company Name:	Mission Pharmacal Company
Address:	38505 Interstate Highway 10, Boerne, Texas 78006
SAM UIE:	JH4RHQNN5G48
DUNS:	008117095
Point of Contact:	Ronald Pitchford, Vice President - Commercial Division
Phone Number:	210-581-0611
E-mail Address:	ron.pitchford@missionpharmacal.com
Web Page URLs:	https://missionpharmacal.com/ and https://missioncdmo.com/
NAICS Code:	325412 (Pharmaceutical Manufacturing)

PART II - Optional Supplemental Information for Consideration by the U.S. Government:

Mission Pharmacal Company (Mission) is a privately-owned, vertically-integrated pharmaceutical company founded 78 years ago and still owned and controlled by the same founding family (all U.S. citizens) in the State of Texas, with all of Mission's extensive facilities being centrally located in the U.S. in the State of Texas where Mission researches, develops,

manufactures, warehouses, distributes and sells, nationally and internationally, prescription medicines and non-prescription over-the-counter pharmaceutical products in facilities that are regularly inspected by the U.S. Food and Drug Administration (FDA) and that are compliant under current Good Manufacturing Practices (cGMP). Mission is also a U.S. federal contractor that is fully committed to diversity, equity, inclusion and equal opportunity in all of its activities.

Mission has a very successful, 78-year history of continuous operations that include the following: (i) developing new medicines and medical devices, both internally at Mission's research and development facilities and externally in collaboration with third-parties, (ii) obtaining FDA approval of new pharmaceutical products under New Drug Applications (NDAs) and medical devices under 510(k) applications filed with and approved by the FDA, (iii) obtaining FDA approval of generic versions of reference listed drugs under Abbreviated New Drug Applications (ANDAs) filed with and approved by the FDA, (iv) manufacturing a variety of different pharmaceutical brand name and generic products in large scale and/or small scale, both for Mission and its third-party customers, (v) domestic U.S. and international distribution and sales of products, (vi) sponsoring research at academic universities and commercializing the results, with profit sharing or royalty payments to the universities and other third-party collaborators, (vii) creating and expanding partnerships and collaborations with academic, scientific, medical, business, investment, governmental and other groups to foster innovation, development and commercialization of new pharmaceutical products and medical devices, (viii) employing and training a wide variety of skilled and unskilled people from all socio-economic levels of society, and (ix) always successfully passing inspections by the FDA and Texas regulatory agencies.

Mission's extensive facilities include (i) 40+ acres of land owned by Mission at 38505 Interstate Highway 10, Boerne, Texas 78006 (just a few minutes north from San Antonio - see the aerial pictures shown at the end of this RFI response and see also Google maps at https://maps.app.goo.gl/LXYPUJddFEJXT5Mg8), on which Mission's 275,000+ square feet of existing research and development laboratories, manufacturing facilities and distribution center are located (with significant room for expansion as reflected by the open, undeveloped areas of land shown in the attached aerial pictures at the end of this RFI response) at which Mission previously manufactured and sold billions of units of prescription medicines and non-prescription over-the-counter pharmaceutical products on an annual basis before the COVID-19 virus pandemic in the year 2020 and at which Mission currently manufactures and sells millions of units of prescription medicines and non-prescription over-the-counter pharmaceutical products on an annual basis (collectively "Mission's Current Campus"), and (ii) 2.5+ acres of land owned by Mission at 1325 East César Chávez Blvd, San Antonio, Texas 78210 (see the aerial picture at the end of this RFI response), on which Mission's 33,000 square feet of prior laboratories and manufacturing facilities were previously located and at which Mission has the ability to develop renewed facilities ("Mission's Former Campus"), near the Alamodome (see also Google maps at https://www.google.com/maps/place/Mission+Pharmacal/@29.4111533,-98.4746371,18z/data=!4m15!1m8!3m7!1s0x865cf5e2bb01afc1:0xb3ab21f0b97f9612!2sDignowity+Hill,+San+Antonio,+TX!3b1!8m2!3d29.42507!4d-98.4732518!16s%2Fg%2F1tr7jtgj!3m5!1s0x865cf61a5aa2e579:0x77b58d38d3649d3c!8m2!3d29.4110746!4d-98.4754956!16s%2Fg%2F11cjp94lvd?entry=ttu).

Mission has a long history of developing, manufacturing and selling new prescription drugs under NDAs approved by the FDA and new generic versions of reference listed drugs under ANDAs approved by the FDA, as well as developing and manufacturing prescription medicines and non-prescription over-the-counter pharmaceutical products for Mission and its third-party contract manufacturing customers. The products currently being manufactured by Mission are focused on the dosage forms of liquid solutions, semi-solids (creams, lotions and gels), and oral solid dosages (tablets). As a result, Mission has focused this response to the RFI from HHS on such dosage forms that are currently being made by Mission. However, Mission is not limited to such dosage forms of products because Mission is also able to develop and manufacture different types of products if there is market demand or governmental demand for a sufficiently high production volume in units of finished products and reasonable prices associated with such products to justify Mission manufacturing such products. Mission also currently operates on a 4-day work week schedule, so Mission could also increase its product production capacities and capabilities by adding more labor and purchasing additional production machinery on a cost-sharing basis with the U.S. Government to further expand the already significant production capacities and capabilities of Mission.

PART III - Responses to Requested Information - Technical Questions under Section 4.A of the RFI:

Mission has the capability and desire to make at least the four (4) below products as listed in the RFI from HHS, all as explained in greater detail herein:

1. Amoxicillin
2. Azithromycin

3. Doxycycline

4. Trimethoprim/Sulfamethoxazole

Although Mission has previously manufactured and sold anti-microbial products, Mission does not currently manufacture the above listed products, but Mission can develop, manufacture and sell any and/or all such products on a large-scale commercial basis as described in further detail in this RFI response. The following summarizes Mission's capabilities with respect to each such product in response to Section 4.A.i of the RFI:

a. U.S. Regulatory Holdings: Mission does not currently own a Drug Master File (DMF), NDA or ANDA for any of the above-listed products, but Mission has been successful in filing for and obtaining FDA approvals of NDAs and ANDAs, as well as Mission has previously manufactured and sold other anti-microbial products, so Mission believes from its experience that Mission could file for and obtain FDA approval of an ANDA for each of the above-listed products within approximately 24 months starting from the time of commencement of Mission's efforts and ending at the time of FDA approval of the ANDA to be filed by Mission for each such product, after which Mission could promptly commence large scale commercial production and sales of the products. Mission has also previously purchased ANDAs for products that were thereafter manufactured by Mission after the usual technical transfer process of approximately 12 months. Mission can accelerate and shorten such respective 12 to 24 month time periods with financial funding from the U.S. Government to be used by Mission to hire additional employees and acquire more high-speed production equipment so that Mission could manufacture the above-listed products sooner on a population-scale basis.

b. Production Scale: All activities can be conducted on Mission's Current Campus that consists of 40+ acres of land on which Mission has 275,000+ square feet of existing

facilities in operation and on which property Mission has extensive room for expansion of activities in existing buildings and on undeveloped portions of land on Mission's property as described hereinabove and as shown in the aerial pictures of Mission's Current Campus at the end of this RFI response. Prior to the COVID-19 virus pandemic in the year 2020, Mission manufactured and sold billions of units of prescription medicines and non-prescription over-the-counter pharmaceutical products on an annual basis at Mission's Current Campus. After the COVID-19 pandemic, Mission currently manufactures and sells millions of units of prescription medicines and non-prescription over-the-counter pharmaceutical products on an annual basis at Mission's Current Campus. So, Mission is highly capable of manufacturing the above-listed products on a population-scale basis.

c. Manufacture Readiness Level (MRL): Mission has an extensive list of manufacturing equipment on which Mission can make the above-listed products on a commercial, population-scale basis, including but not limited to the following: (i) for liquid products, Mission has two (2) 10,000 Liter mixing tanks, two (2) additional 10,000 Liter holding tanks, multiple 1,500 Liter liquid compounding vessels, two (2) high speed liquid product filling lines, and other related equipment; (ii) for oral solid dosage (OSD) products (tablets), Mission has five (5) 2-sided Fette presses and one (1) 1-sided Fette press with the capability to produce more than 4+ billion tablets per year on a single shift of employees working only four (4) days per week (thus production volume can be substantially increased by Mission adding additional shifts of employees), plus large amounts of related equipment for weighing, compounding, coating, four (4) OSD packaging equipment lines, and other related equipment; and (iii) for semi-solid products (lotions, creams, gels, etc.), Mission has two (2) 5,000 Liter mixing tanks, high speed filling equipment lines and other related equipment. Mission also has multiple

mixing rooms to accommodate high production throughput needs with high and low shear mixing with heating and cooling capabilities, as well as Mission has high-speed filling machines and packaging equipment with already completed serialization and aggregation compliance with the federal Drug Supply Chain Security Act (DSCSA). The total production time from purchase order to fulfillment of each product depends on the production volumes of the number of units of finished dosage forms (FDF) of each product that are desired in each purchase order because Mission is in control of the production schedule of every product made by Mission for itself and/or its customers, so Mission can always prioritize and accelerate particular products in the production schedule to be made on a sooner in time basis. Mission could also further accelerate production schedules with additional employees that could be hired by Mission and additional production machinery that could be purchased by Mission, in each case on a cost-sharing basis with the U.S. Government.

d. Key Equipment or Material(s): All items needed to make the products can be obtained within the U.S., except for the following items that will need to be imported from the following foreign (non-U.S.) sources to make each of the following products:

1. Amoxicillin – API is available from Spain, Netherlands and Israel. The excipients are available from Czechia, Germany, South Korea, Singapore and Taiwan.

2. Azithromycin – API is available from multiple sources in Israel and India. The excipients are available from Czechia, Germany, South Korea, Singapore and Taiwan.

3. Doxycycline – API is available from Portugal, India and Macau. The excipients are available from Czechia, Germany, South Korea, Singapore and Taiwan.

4. Trimethoprim/Sulfamethoxazole – Trimethoprim API is available from Israel, India and China. Sulfamethoxazole API is available from India and China. The excipients are available from Germany and Singapore.

Mission already owns and operates all of the key equipment on Mission's Current Campus that will be needed to manufacture the subject products on a population-scale basis, which includes high shear granulators, fluid bed dryers, top spray fluid bed systems, V-blenders, tablet presses, tablet coating pans and bottle filling packaging lines. However, Mission recommends that dedicated areas on Mission's Current Campus be used to only manufacture the subject products, which could be done on an expedited basis by using dedicated modular clean rooms that can be obtained and installed within 3 months for weighing of ingredients and manufacturing the products, and/or which could be done on a more permanent basis in dedicated existing buildings or new buildings to be constructed on the undeveloped areas on the 40+ acres of Mission's Current Campus. After the installation of modular clean rooms and/or the construction of permanent facilities dedicated to making such products, the required validation process for any new equipment and related manufacturing processes would take up to 3 more months. Thus, Mission could be ready on an expedited basis in this matter, which time period could be further accelerated with cost-sharing financial arrangements between Mission and the U.S. Government to purchase additional equipment and hire additional employees. In addition, the preparation, submission and FDA review time of an ANDA, including the FDA required bioequivalence in vivo study, typically takes 24+ months, but a purchased ANDA product can usually be produced and sold in the market within 12 months of acquisition.

e. Present Operating Capacities: Misson can produce millions of units of FDF of each of the above-listed products on an annual basis with the existing machinery at Mission's

Current Campus. If a larger quantity of any product is needed for population-scale requirements, then such larger quantities of such product could be made by Mission with a financial investment on a cost-sharing basis with the U.S. Government to purchase additional equipment and hire additional employees. Mission currently operates on a single shift of employees working only four (4) days per week that was instituted by Mission decades ago, so production volumes could be substantially increased by Mission simply adding additional shifts of employees working on Mission's existing equipment. Mission could further substantially increase its production volumes by Mission purchasing additional high-speed equipment and machinery to complement the substantial amount of existing machinery and equipment already owned and operated by Mission.

f. Production at Domestic Location: The procurement process for all items needed for each product and all production of each product would occur domestically in the U.S. at only Mission's Current Campus in the State of Texas. However, the procurement process will include the needed procurement of the subject items from foreign (non-U.S.) sources as listed above under Subsection d. "Key Equipment or Material(s)" for each of the subject products. In order for all items needed for each product to be sourced and made only in the U.S., then the U.S. Government would need to grant waivers or exceptions to allow the API and excipients to be made in the U.S. since the processes to make such items can involve key starting materials, organic solvents, specialized glass lined vessels, heating and cooling devices, catalysts, purification equipment (i.e., recrystallizers), dryers, sifters, milling equipment and packaging equipment that generate noise, fumes and chemical waste. Mission is prepared for such activities because Mission already has a fully equipped analytical laboratory with modern instruments and

equipment for the characterization and testing of APIs and excipients which are needed for manufacture of the subject products in the U.S.

g. Effects of COVID-19: During the COVID-19 virus pandemic, Mission remained in continuous operation as an essential business making needed medicines for the U.S. population. Mission adjusted its business as a result of the COVID-19 virus pandemic by increasing the number of different global sources of supply of the various items needed by Mission to make the different pharmaceutical products manufactured by Mission for itself and its customers. Mission has developed alternative sources of supply of the various items needed to develop and manufacture the products made by Mission for itself and its customers in the event of future pandemics or conflicts in various parts of the world.

PART IV - Responses to Requested Information - Technical Questions under Section 4.A.ii through Section 4.A.vii of the RFI:

1. **Section 4.A.ii of RFI - Existing Facilities for Expanded Production.** Mission has room for substantial expansion of production activities on Mission's Current Campus in existing buildings and on the large amount of undeveloped land on the 40+ acres of land on Mission's Current Campus property as shown in the aerial pictures attached at the end of this RFI submission. Mission could also utilize Mission's Former Campus that consists of 2.5 acres of land on which Mission has 33,000 square feet of prior operating facilities, which location is currently dormant, but which could be repurposed or modernized with additional financial investment to make additional products for the U.S. population, as shown in the aerial picture of Mission's Former Campus attached at the end of this RFI submission. The time and cost needed

to repurpose or modernize Mission's Former Campus will be dependent on the products and production volumes to be made at that location.

2. **Section 4.A.iii of RFI - Existing Customer Base and Ability to Include New Medicines in Existing Sales and Marketing Operations.** Mission manufactures very large amounts of products on an annual basis for Mission and its customers under agreements that require confidentiality regarding such customers and their respective products, so Misson cannot disclose such details in this RFI response. However, Mission has the ability and manufacturing capabilities to include new products in Mission's existing product development, manufacturing, sales, marketing and distribution operations.

3. **Section 4.A.iv of RFI – Forecast Concerns and Possible Challenges to Maintain Current Manufacturing Capabilities.** There are no challenges that may impact Mission's ability to maintain its current manufacturing capabilities and/or its capacities, other than potential supply chain issues that may arise with respect to items needed from foreign (non-U.S.) suppliers for the subject products described in this RFI response.

4. **Section 4.A.v of RFI - Status of Manufacturing Alliances.** Mission is a vertically integrated company that researches, develops, manufactures, warehouses, distributes and sells products for Mission and its customers, including but not limited to Mission being the contract manufacturing organization (CMO) for Mission's customers. Mission's research and development department also develops new prescription pharmaceutical products, generic versions of existing reference listed drugs (RLDs), and non-prescription over-the-counter

products for Mission and its customers. Mission does not depend upon any alliance with any other entity in Mission's independent and vertically integrated ability to research, develop, manufacture, warehouse, sell and deliver any products selected by Mission, which capabilities and capacities of Mission could be enhanced, expanded and accelerated with financial assistance in cost-sharing arrangements between Mission and the U.S. Government.

5. **Section 4.A.vi of RFI – Capital Assets Associated with Production/Proposal.**

Mission already owns, operates and maintains all of the capital assets needed for Mission to develop and make the FDFs of each of the products listed hereinabove. Mission does not make the API or any other components needed to develop or manufacture such products. The API and other components for each such product and its country of origin are set forth earlier in this RFI response.

6. **Section 4.A.vii of RFI – No Production Bottlenecks.** Mission does not have any production bottlenecks. Mission currently operates on a single shift of employees working only four (4) days per week that was instituted by Mission decades ago, so production volumes could be substantially increased by Mission simply adding additional shifts of employees to work on exiting equipment and machinery already owned and operated by Mission. Mission could also substantially increase production volumes of any product by the purchase of additional machinery by Mission with financial funding from the U.S. Government.

PART V - Responses to Requested Information – General Questions under Section 4.B of the RFI:

1. **Section 4.B.i of RFI – Challenges and Mitigation of Challenges.** Mission does not foresee any challenges to Mission being able to produce and sell the products listed above in this RFI response after Mission either files and receives FDA approval of Mission's ANDA for each such product or Mission acquires existing ANDAs for such products. Mission has successful experience in all such pathways to internally develop or externally acquire prescription drugs and thereafter produce and sell such products on a national and international basis. The timing of Mission's commencement of commercial production of such products on a population-scale basis could be significantly accelerated by Mission with financial funding from the U.S. Government that would be used by Mission to purchase additional high speed production machinery and hire additional shifts of employees to bring such products to the commercial market sooner for the benefit of the U.S. population.

2. **Section 4.B.ii of RFI – Investments by the U.S. Government to Promote Domestic Manufacturing of Critical Inputs to Produce the Listed Products.** The investments that could be made by the U.S. Government to promote the expansion of domestic manufacturing of the precursors, key starting materials (KSMs), intermediates, drug substances, drug products and critical inputs that are used to produce the medicines listed above are described above under Section III, subsections (d) and (f) thereof, of this RFI response.

3. **Section 4.B.iii of RFI – Contract Preference for OTA and Rationale.** Mission would prefer an Other Transactions Agreement (OTA) versus a FAR-based contract for this effort because an OTA is much more direct and expedient than a FAR-based contract.

4. **Section 4.B.iv of RFI – Cost Sharing Versus Loans.** Mission does not desire to receive any loans, loan guarantees or other debt in this matter. Mission prefers a cost-sharing arrangement, a financial grant or other financial arrangement with the U.S. Government that does not involve financial repayments by Mission to the U.S. Government or any third-party. However, Mission could develop, manufacture and sell the subject products to the U.S. Government and the U.S. population on a discounted basis in consideration for financial investments by the U.S. Government to accelerate the time within which Mission could commercially produce and sell such products to the U.S. Government and the U.S. population because such financial assistance from the U.S. Government could be used by Mission to hire more people and purchase more high speed machinery to accelerate and shorten the time within which Mission could develop generic versions of the subject products and file the ANDAs to receive FDA approval for Mission to thereafter manufacture and sell such products, which is a process in which Mission has good past and on-going experience and success.

5. **Section 4.B.v of RFI – Five-Year Plan after U.S. Government Funding.** Mission has been in continuous, successful operation for 78+ years as a self-sustaining company that does not require any funding from the U.S. Government. However, any financial funding provided by the U.S. Government to Mission could be used by Mission to accelerate all of Mission's activities as described in this RFI response by Mission hiring more people and purchasing more

high-speed machinery to expedite and shorten the time within which Mission could develop generic versions of the subject products and file the necessary ANDAs to receive FDA approval for Mission to thereafter manufacture and sell such products from Mission's Current Campus. In the event the U.S. Government desires to further expand the activities that Mission could perform for the benefit of the U.S. Government and the U.S. population by Mission producing a greater quantity and variety of anti-microbial products from Mission's already extensive operations on Mission's Current Campus, then Mission has a large amount of undeveloped land on Mission's Current Campus that could be used for further expansion of existing or new activities, as well as Mission's Former Campus is currently dormant and available for utilization if needed to support the efforts by the U.S. Government to foster the expanded production of anti-microbials in the United States, which is a matter of vital national security for the health and well-being of the U.S. population, especially at the current time when there are international conflicts actively occurring and/or germinating in various areas around the world that could adversely affect the availability of FDFs of anti-microbial products and/or API and other components needed to make the FDFs of such important products. Previously, when the COVID-19 virus pandemic first began to significantly occur in the U.S. in March 2020, the countries of China and India initially stopped exporting API and FDF of anti-microbial medicines, which highlighted the vulnerability of the U.S. for failing to make all (or as much as possible) of the items needed to produce anti-microbial medicines within the U.S. for national security and national health reasons.

6. <u>Section 4.B.vi of RFI – Cost Estimates for the Total Project.</u> Mission is able to perform all activities in this matter without any financial assistance from the U.S. Government.

Mission has successful experience in developing, manufacturing and selling prescription anti-microbial drugs, which Mission has done on its own in the past and which Mission again can do on a unilateral basis now and in the future. Mission merely needs either a product purchase commitment from the U.S. Government or a financial funding agreement (preferably an OTA) from the U.S. Government to provide Mission with a sufficient return on investment (ROI) for the time and money that will need to be invested to bring the subject products to market in this project. However, Mission and the U.S. Government could invest in this project together on a cost-sharing basis to accelerate and expand Mission's activities with financial assistance from the U.S. Government.

PART VI – Summary Conclusion:

In summary, Mission is ready, willing and able to promptly work with the U.S. Government for Mission to develop, produce and supply on a population-scale basis the subject prescription anti-microbial medicines for the strategic national security needs of the U.S. Government and the healthcare needs of the U.S. population. Mission strongly recommends that Mission and the U.S. Government promptly commence discussions together regarding the acceleration and shortening of the time periods within which Mission can commence large scale commercial production of such vital anti-microbial products under a financial cost-sharing arrangement between the U.S. Government and Mission. Time is of the essence in this matter, especially in light of the increased problems in the Far East and the Middle East areas of the world, where many of the subject products are currently made to the strategic and national security detriment of the U.S., which problem can be solved by the U.S. Government and Mission promptly working together as described above in this RFI response.

Mission’s Current Campus

Mission's Former Campus