

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11771

FDA 224-75-3001

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for bid and contracts. These reports will be furnished within 30 days or an earlier mutually agreed upon time. If written reports cannot be furnished within the agreed upon time, FDA will telephone results of inspection to DSA and follow with written confirmation.

B. DSA agrees:

1. To furnish written requests for inspection services.
2. To furnish FDA with an annual estimate of the number of inspections to be required, the estimate not to be binding on either party.
3. To notify FDA of any specific changes in DSA contracting and purchasing arrangements which might affect this agreement.
4. To furnish FDA concurrent with requests for foreign inspection any background or inspectional data, as available in-house, for any foreign inspection conducted by FDA under this agreement.
5. To furnish FDA copies of all current drug and pharmaceutical specifications used in procurement. This will include, but not be limited to, Federal specification, military purchase descriptions, etc.

C. Revisions

1. Additional procedures and revisions as may be necessary for the implementation of this agreement and to effectuate the intention of the parties may be developed jointly by FDA and DSA. Such revisions shall become effective on such date as is mutually agreed upon by the parties.
2. In the event that the time requirements expressed herein cannot be met by FDA, the DSA will be advised promptly.

D. Other Provisions

1. In the event FDA has inspected the facilities of the foreign manufacturer within one (1) calendar year of the date of the inspection request from DSA, a written report of that inspection will be furnished DSA. DSA will review the report and if additional information is required, FDA will furnish the required information or perform the supplementary inspection necessary.