CPG Sec. 100.700 GWQAP Pre-Award Evaluation - Inadequate Information to Evaluate Prospective Supplier

BACKGROUND:

One of FDA's responsibilities under the Government-Wide Quality Assurance Program for medical products is to perform pre-award evaluations to determine the capability of prospective suppliers to furnish products of acceptable quality. In performing this assessment, FDA evaluates all information available to the agency bearing on the quality capability of the firm with respect to the product(s) involved. When *current* reliable information is not in the agency's file, an on-site inspection is made to obtain whatever information is considered necessary to properly evaluate the prospective supplier. When performing these inspections, the FDA investigator is acting both under the authority of the Federal Food, Drug, and Cosmetic Act (Act), and related statutes, and as an agent of the contracting officer in the purchasing agency.

There are times when FDA does not have in its files, and is unable to obtain through inspection, information that is crucial in performing a proper quality evaluation. Examples of such instances include the following: *

- A firm is not operating, and FDA is therefore not able to conduct an adequate inspection to obtain information regarding manufacturing practices and procedures necessary for determining the acceptability of manufacturing operations and controls.
- A contractor who bids on a government contract uses a distributor to supply the actual product. When contacted by the FDA to obtain the name and location of the actual manufacturer of the product, the distributor refuses to reveal his source, claiming that it is proprietary information that, if revealed, may put him at a competitive disadvantage.*

POLICY

When FDA determines it is unable to perform a proper evaluation of a prospective contractor because the agency does not have, or is not able to obtain, the information necessary for performing the evaluation, FDA will report to the purchasing agency that based upon all the

available information, FDA is not able to perform a proper evaluation and therefore cannot make recommendations on the acceptability of the prospective contractor as a supplier. This report will include the reasons why information necessary for proper evaluation is not available.

Material between asterisks is new or revised

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