YOU CAN REFER BACK TO ANY OF THESE DEFINITIONS BY CLICKING THE "DEFINITIONS OF KEY TERMS" LINK AT THE TOP OF EACH SURVEY PAGE. YOU DO NOT HAVE TO READ THEM ALL NOW.

DEFINITIONS OF KEY TERMS FOR FDA SURVEY

TERM	DEFINITION
Audit [of suppliers of components and container/closures]	Supplier auditing is the systematic inspection and evaluation of a supplier's quality management system, including their practices, products, and documentation. Supplier audits often require site visits.
Drug product	For this survey, "drug product" includes the following types of products *in their final marketed form:* prescription drugs, biological products, over-the-counter drugs, and other products that are: 1. Intended to diagnose, cure, mitigate, treat, or prevent disease in animals or humans; *or* 2. Non-food products intended to affect the structure or any function of the body of humans or other animals. Some products meet this definition of drug products because they are intended to treat a condition and/or are intended to affect the structure or any function of the body. For example, an antidandruff treatment is a drug because its intended use is to treat dandruff. Other products that fall into this category are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims.
Drug product processing facility	A drug product processing facility is any facility that manufactures, packs or re-packs, labels or re-labels, tests, or sterilizes any prescription or OTC drug for use by humans or animals.
Drug product component	Each active pharmaceutical ingredient and inactive agent (including fillers and coloring agents) that are combined to form a drug product.
Drug product container and closure	The packaging that contains and protects the drug product as it is marketed and delivered to end-user health care providers.
Established supplier (of drug components or containers and closures)	A company that has supplied your facility with specific drug components or containers and closures in the past and has been qualified by your facility or parent company as a supplier of those previously shipped products.
Gross revenue	The total earnings of a company through sales, services, and any other income generating activity, before expenses such as labor and material costs, taxes, interest, etc. are deducted.
Joint review meetings	Meetings scheduled between members of facility executive management, departmental managers, and shop floor personnel meant to discuss, anticipate, and inform everyone about current and potential issues.
Labeling	Any written, printed, or graphic material containing drug information that is affixed to or accompanies any drug product or any of its containers or wrappers.
Management with executive responsibility	Any employee who has the authority to provide resources, to establish or make changes to organizational structure, buildings, facilities, equipment, or the manufacture, processing, packing, or holding of a drug product.
New drug product component	A "new drug product component" shipped from a "qualified supplier" is the first time you receive a shipment of a specific drug product component from a supplier that has been qualified by your facility or company.
New container and closure	A "new container and closure" shipped from a "qualified supplier" is the first time you receive a