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(Aseptic Processing Guideline). This revision updates and clarifies the 1987 guidance. For sterile drug products subject to a new or abbreviated drug application (NDA or ANDA) or a biologic license...

Guidance for Industry

Aseptic processing equipment sterilization procedures often use steam or hot water under pressure. Packaging equipment and packaging materials are sterilized with various medium or combination of...

Aseptic Processing and Packaging for the Food Industry | FDA

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Aseptic processing and packaging means the processing and packaging of a commercially sterile product into sterilized containers followed by hermetic sealing with a sterilized closure in a manner which prevents viable microbiological recontamination of the sterile product.

Food Hygiene in Aseptic Processing and Packaging Systems

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