If a desiccant or other absorbent material is used, the composition should be provided (or an appropriate DMF referenced). The component should differ in shape and/or size from the tablets or capsules with which it is packaged. This will help distinguish between the component and the dosage form. Because these are considered primary packaging components, appropriate tests and acceptance criteria to establish suitability should be provided (see Table 7 for additional information).

Table 7
Information That Typically Should Be Submitted for Solid Oral Drug Products and Powders

Description	Overall general description of container closure system, plus: For Each Packaging Component: • Name, product code, manufacturer • Materials of construction • Description of any additional treatments
Suitability	Protection: (by each component and/or the container closure system, as appropriate) • Light exposure • Moisture permeation • Seal integrity or leak tests for unit-dose packaging Safety: (for each material of construction, as appropriate) • Chemical composition of all plastics, elastomers, adhesives, etc.[a] • For tablets, capsules, and powders, appropriate reference to the indirect food additive regulation may be submitted, but may not be appropriate for Powders for Reconstitution. • For rayon and cotton fillers, data from USP monographs. For non-USP materials, data and acceptance criteria should be provided. • For dessicants and other absorbent materials: the size and shape should differ from that of the dosage form. Compatibility: (on each component or the packaging system) • For glass and plastic containers, data from USP Containers[b] testing. Performance: (on each component or the packaging system, as appropriate) • Functionality and/or drug delivery, as appropriate
Quality Control	For Each Packaging Component Received by the Applicant: • Applicant's tests and acceptance criteria[c] • Dimensional (drawing) and performance criteria • Method to monitor consistency in composition, as appropriate For Each Packaging Component Provided by the Supplier: • Manufacturer's acceptance criteria for release, as appropriate • Description of manufacturing process, as appropriate
Stability	• See section III.C.4

[a] Including any additives used in the manufacture of a packaging component

[b] Testing of plastics should be performed on the packaging component, not on the unformed resin.

[c] Note that applicant's acceptance tests may include, among others, test parameters indicated under the description, suitability, and quality control sections of this table.

H. Other Dosage Forms

The CGMP requirements for container closure systems for compressed medical gases are described in 21 CFR 210 and 211. The containers are regulated by the U.S. Department of Transportation. For more detailed information refer to the CDER *Compressed Medical Gas Guideline* (February 1989).

When submitting information for a drug product or dosage form not specifically covered by the sections above, a firm should take into consideration: (1) the compatibility and safety concerns raised by the route of administration of the drug product and the nature of the dosage form (e.g., solid or liquid-based); (2) the kinds of protection the container closure system should provide to the dosage form; and (3) the potential effect of any treatment or handling that may be unique to the drug product in the packaging system. Quality control procedures for each packaging component should ensure the maintenance of the safety and quality of future production batches of the drug product.

IV. POSTAPPROVAL PACKAGING CHANGES

For an approved application (NDA, ANDA or BLA), a change to a container closure system, to a component of the container closure system, to a material of construction for a component, or to a process involving one of the above must be reported to the application. The filing requirements are specified under 21 CFR 314.70 (supplements and other changes to an approved application) for an NDA or ANDA, and under 21 CFR 601.12 (changes to an approved application) for a BLA. The submission should address the items described and discussed in sections III.B and III.C of this guidance. The Agency intends to provide additional guidance on postapproval changes in container closure systems in the future.

V. TYPE III DRUG MASTER FILES

A. General Comments

The responsibility for providing information about packaging components rests foremost with the applicant of an NDA, ANDA or BLA, or the sponsor of an IND. This information may be provided to the applicant by the manufacturer of a packaging component or material of construction and may be included directly in the application. Any information that a manufacturer does not wish to share with the applicant or sponsor (i.e., because it is considered proprietary) may be placed in a Type III DMF and incorporated into the application by a letter from the manufacturer to the applicant which authorizes reference to the DMF. The letter of authorization should specify the firm to whom authorization is granted, the component or material of construction being described, and where the information and/or data is located in the file by page number and/or date of submission. This last item is especially important for files that contain information on multiple components or have several volumes.

Information in a Type III DMF is not restricted to data of a proprietary nature. DMF holders may include in their files as much or as little information as they choose. In addition, a manufacturer of a packaging component is not required to maintain a Type III DMF. Without a DMF there is no procedure for the Agency to review proprietary information except by submission to the application.

The Agency ordinarily reviews a DMF only in connection with an application (IND, NDA, ANDA, or BLA). If the combined information from the application and the DMF is not adequate to support approval of the application or safety for the IND, then the Agency may request additional information from the applicant and/or the DMF holder, as appropriate.

In the event of a change in the DMF, the holder of a DMF must notify the holder of each application supported by the DMF (21 CFR 314.420(c)). Notice should be provided well before the change is implemented to allow the applicant or sponsor enough time to file a supplement or an amendment to the affected application.

General information on format and content of a DMF and a LOA may be found in the CDER *Guideline for Drug Master Files* (September 1989).

B. Information in a Type III DMF

Section III of this guidance describes the kind of descriptive, suitability, and quality control information which the Agency usually reviews concerning packaging components and materials of construction for drug products. The following are examples of the items that have been submitted via a Type III DMF.

1. Descriptive Information:

    a. General description of the component and the address of the manufacturing site

    b. Description of the manufacturing process for a packaging component and operations performed after manufacture, but prior to shipment (washing, coating, sterilization or depyrogenation)

    c. Description of the acceptance, in-process, and release controls for materials of construction, the manufacturing process, and the finished product (component part or assembled component)

    d. Characterization of the key properties

2. Information About Suitability

a. Protection provided by the component

b. Safety information on the materials of construction or the finished component

c. Compatibility of the materials of construction or the finished component with the specific dosage form, the specific drug product, or equivalent materials

3. Information About Quality Control:

a. Dimensional (an engineering drawing) and performance criteria for the component

b. A description of the quality control measures used to maintain consistency in the physical and chemical characteristics of packaging components

c. A summary of the quality assurance/quality control criteria when release of the component is based on statistical process control

VI. BULK CONTAINERS

A. Containers for Bulk Drug Substances

Drug substances are generally solids, but some are liquids or gases.

The container closure system for storage or shipment of a bulk solid drug substance is typically a drum with double LDPE liners that are usually heat sealed or closed with a twist tie. A desiccant may be placed between the bags.

The drum provides protection from light and mechanical strength to protect the liner during shipment and handling. The majority of the protection from air and moisture is provided by the liner. Because LDPE is not a particularly good moisture barrier, a drug substance that is moisture sensitive may need additional protection. An alternative to a LDPE bag is a heat-sealable laminate bag with a comparatively low rate of water vapor transmission.

Qualification of the packaging system is usually based on establishing compatibility and safety of the liner but may also include characterization for solvent or gas transmission (see section III.B).

The container closure system for the storage or shipment of a bulk liquid drug substance is typically plastic, stainless steel, a glass-lined metal container, or an epoxy-lined metal

container with a rugged, tamper-resistant closure. Qualification of the container closure system may include characterization for solvent and gas permeation, light transmittance, closure integrity, ruggedness in shipment, protection against microbial contamination through the closure, and compatibility and safety of the packaging components as appropriate (see section III.B).

The application (or Type II DMF) should include a detailed description of the complete container closure system for the bulk drug substance as well as a description of the specific container, closure, all liners, inner seal, and desiccant (if any), and the composition of each component. A reference to the appropriate indirect food additive regulation is typically considered sufficient to establish the safety of the materials of construction (also note the discussion on this subject in section III). The tests, methods, and criteria for the acceptance and release of each packaging component should be provided.

Stability studies to establish a retest period for bulk drug substance in the proposed container closure system should be conducted with fillers or desiccant packs in place (if used). Smaller versions which simulate the actual container closure system may be used. Stability recommendations for container closure systems of different types are described in the *Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics* (February 1987).[23]

Container closure systems for compressed medical gases are discussed in section III.H.

B. Containers for Bulk Drug Products

A container closure system for bulk drug products may be used for storage prior to packaging or for shipment to repackagers or contract packagers. In all cases, the container closure system should adequately protect the dosage form and should be constructed of materials that are compatible and safe.

Container closure systems for on-site storage have generally been considered a CGMP issue under 21 CFR 211.65. However, if a firm plans to hold bulk drug products in storage, then the container closure system and the maximum storage time should be described and justified in the application. In addition, stability data should be provided to demonstrate that extended storage in the described containers does not adversely affect the dosage form. Even when the storage time before packaging will be short, a firm should use a container closure system that provides adequate protection and that is manufactured from materials that are compatible and safe for the intended use (see section III.B).

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[23] The 1987 stability guidance will be superseded by the FDA guidance for industry *Stability Testing of Drug Substances and Drug Products,* issued in draft for comment in June 1998, once it is issued in final form.

A container closure system for the transportation of bulk drug products to contract packagers (section II.C.3) should be described in the application. The container closure system should be adequate to protect the dosage form, be constructed with materials that are compatible with product being stored, and be safe for the intended use. The protective properties of the shipping container are verified by the practice of including annual batches of the packaged product in postapproval stability studies.

A container closure system specifically intended for the transportation of a large volume of drug product to a repackager (section II.C.3), whether for a solid or liquid dosage form, is considered a market package. The package should meet the same requirements for protection, compatibility, and safety as a smaller market package;[24] should be included in the stability studies for application approval and in the long term stability protocol; and should be fully described in the application. The length of time that the dosage form will spend in the bulk container may be a factor in determining the level of detail of the supporting information. Two examples of a large-volume shipping package are a 10,000-tablet HDPE pail with tamper-evident closure, and a 10-liter polyethylene terephthalate (PET) container with a screw cap closure with dispenser attachment for a liquid drug product. Both are intended for sale to a mass distribution pharmacy. A special case is the pharmacy bulk package which is described in USP <1>.

[24] FDA *Compliance Policy Guides*, "Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or other Manipulation," Section 446.100, January 18, 1991 (CPG 7132c.06).

ATTACHMENT A[25]

REGULATORY REQUIREMENTS

1. The Federal Food, Drug, and Cosmetic Act

a. Section 501

A drug or device shall be deemed to be adulterated "if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health" (section 501(a)(3)); or "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess (section 501(a)(2)(B)).

b. Section 502

A drug or device shall be deemed to be misbranded:

- "[i]f it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein" (section 502(g))

- "[i]f it is a drug and its container is so made, formed, or filled as to be misleading" (section 502(i)(1))

- "[i]f it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970" (section 502(p))

c. Section 505

"No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug" (section 505(a)).

Section 505(b)(1)(D) requires "a full description of the methods used in, and the

[25] Applicants should check the appropriate sources directly for the most up-to-date information.

facilities and controls used for, the manufacture, processing, and packing of such drug."

2. The Code of Federal Regulations

a. 21 CFR 211 - Current Good Manufacturing Practice for Finished Pharmaceuticals

i. Subpart E, Control of Components and Drug Product Containers and Closures (21 CFR 211.80 - 211.94)

In particular, 21 CFR 211.94 outlines the requirements for drug product containers and closures:

(a) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements.

(b) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

(c) Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to ensure that they are suitable for their intended use.

(d) Standards or acceptance criteria, test methods, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures.

ii. Subpart F, Production and Process Controls (21 CFR 211.100 - 211.115)

iii. Subpart G, Packaging and Labeling Control (21 CFR 211.122 - 211.137)

In particular, 21 CFR 211.132 describes the tamper-resistant packaging requirements for over-the-counter (OTC) human drug products. Most OTC drug products must be packaged in tamper-resistant containers.

b. 16 CFR 1700-1702 - Special Packaging

The U.S. Consumer Product Safety Commission (CPSC) is responsible for enforcing the Poison Prevention Packaging Act of 1970 (PPPA). The PPPA requires special packaging of hazardous household substances to protect children

from serious personal injury or serious illness from handling, using, or ingesting the substances. Drug products containing controlled substances, most human oral prescription drug products (including oral investigational drugs used in outpatient trials), and OTC drug preparations containing aspirin, acetaminophen, diphenhydramine, liquid methyl salicylate, ibuprofen, loperamide, lidocaine, dibucaine, naproxen, iron, or ketoprofen, require special packaging (16 CFR 1700.14).

Special packaging is defined under 15 U.S.C. 1471(2)(4), 16 CFR 1700.1(b)(4), and 21 CFR 310.3(l). Regulations issued under the PPPA establish performance standards and test methods that determine if a packaging system is child-resistant and adult-use-effective (16 CFR 1700.15 and 16 CFR 1700.20, respectively). Except as noted below, all PPPA-regulated substances must be in packaging systems that comply with these special packaging standards. The standards apply to both reclosable and nonreclosable packaging systems (unit-dose packaging).

There are several situations where child-resistant packaging for drug products is not required. Manufacturers and packagers of bulk-packaged prescription drug products do not have to use special packaging if the drug is intended to be repackaged by the pharmacist. However, the manufacturer or packager is responsible for child-resistant packaging if the drug product is intended to be dispensed to the consumer as packaged without repackaging by the pharmacist (16 CFR 1701.1). Prescribed drugs that are dispensed for use within institutions such as hospitals and nursing homes do not require child-resistant packaging. However, any prescriptions dispensed to patients upon their release for their use at home would be subject to the PPPA packaging requirements. In addition, drug product manufacturers are not required to provide child-resistant packaging for prescription drug samples that are distributed to physicians and other prescribing practitioners (i.e., physician samples).[26]

For OTC preparations, manufacturers or packagers are allowed to market one size in non-child-resistant packaging as long as child-resistant packages are also supplied. The non-child-resistant package requires special labeling (16 CFR 1700.5).

16 CFR 1702 establishes the procedures for petitioning the CPSC for an exemption from the PPPA requirements. Several prescription drugs (e.g., oral contraceptives in mnemonic packages, powdered colestipol, and medroxyprogesterone acetate) have been exempted from the special packaging requirements (16 CFR 1700.14(10)(I)-(xix)). The CPSC is permitted to grant an

[26] *Federal Register*, Volume 49, March 5, 1984, page 8008 (49 FR 8008), "Prescribed Drugs Distributed to Prescribing Practitioners; Withdrawal of Proposed Statement of Policy and Interpretation."

exemption if it finds that packaging is not required to protect children from serious injury, or that special packaging is not technically feasible, practicable, or appropriate for that product.

For additional information regarding these packaging requirements and the protocol test methods, please contact the CPSC. Their website is located at www.cpsc.gov and their hotline is 1-800-638-2772.

c. 21 CFR 174-186 - Indirect Food Additive Regulations

Regulations that are applicable to packaging components are:

i. Part 174 - Indirect Food Additives: General

ii. Part 175 - Indirect Food Additives: Adhesives and Components of Coatings

e.g.,	175.105	Adhesives
	175.300	Resinous and polymeric coatings

iii. Part 176 - Indirect Food Additives: Paper and Paperboard Components

e.g.,	176.170	Components of paper and paperboard in contact with aqueous and fatty foods
	176.180	Components of paper and paperboard in contact with dry food

iv. Part 177 - Indirect Food Additives: Polymers

e.g.,	177.1380	Fluorocarbon resins
	177.1520	Olefin polymers
	177.1630	Polyethylene phthalate polymers

v. Part 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

vi. Part 180 - Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending Additional Studies

e.g.,	180.22	Acrylonitrile copolymers

vii. Part 182 - Substances Generally Recognized as Safe

e.g.,	182.70	Substances migrating from cotton and cotton fabrics

used in dry food packaging

182.90 Substances migrating to food from paper and paperboard products

viii. Part 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe (GRAS)

e.g., 186.1673 Pulp

d. Biologics Provisions, 21 CFR 600, Subpart B, Establishment Standards

i. 21 CFR 600.11(h) - Containers and Closures

ii. 21 CFR 601.2 - Applications for Licenses; Procedures for Filing

e. Other Sections

i. 21 CFR 201 - Labeling

ii. 21 CFR 310.509 - Parenteral drug products in plastic containers

iii. 21 CFR 200.50(a)(3) - Containers of ophthalmic preparations

3. U.S. Pharmacopeia/National Formulary

The following sections are applicable to packaging components:

a. General Notices - PRESERVATION, PACKAGING, STORAGE, AND LABELING

b. General Tests and Assays

<1>	Injections
<51>	Antimicrobial Preservatives - Effectiveness
<61>	Microbial Limit Tests
<71>	Sterility Tests
<87>	Biological Reactivity Tests, in vitro
<88>	Biological Reactivity Tests, in vivo
<161>	Transfusion and Infusion Assemblies
<381>	Elastomeric Closures for Injections • Biological Test Procedures • Physicochemical Test Procedures
<601>	Aerosols
<661>	Containers

- Light Transmission
- Chemical Resistance - Glass Containers
- Biological Tests - Plastics and Other Polymers
- Physicochemical Tests - Plastics
- Containers for Ophthalmics - Plastics
- Polyethylene Containers
- Polyethylene Terephthalate Bottles and Polyethylene Terephthalate G Bottles
- Single-Unit Containers and Unit-Dose Containers for Nonsterile Solid and Liquid Dosage Forms
- Customized Patient Medication Packages

<671> Containers - Permeation
- Multiple-Unit Containers for Capsules and Tablets
- Single-Unit Containers and Unit-Dose Containers for Capsules and Tablets

<691> Cotton (or the monograph for Purified Rayon USP)

<771> Ophthalmic Ointments

<1041> Biologics

<1151> Pharmaceutical Dosage Forms

ATTACHMENT B

COMPLIANCE POLICY GUIDES THAT CONCERN PACKAGING
(August 1996)

Compliance Policy Guides are issued by the Division of Compliance Policy (in the Office of Enforcement/Office of Regulatory Affairs). The following is a list of Compliance Policy Guides that concern packaging. Any questions or concerns about the content of any Compliance Policy Guide should be addressed to the Office of Enforcement/Office of Regulatory Affairs/Division of Compliance Policy at 301-827-0420 (telephone), 301-827-0482 (FAX) or www.fda.gov/ora/compliance_ref/cpg/default.html (Internet).

Sub Chapter 410	BULK DRUGS
Sec. 410.100	Finished Dosage Form Drug Products in Bulk Containers - Applications of Current Good Manufacturing Practice Regulations (CPG 7132a.06)
Sub Chapter 430	LABELING and REPACKAGING
Sec. 430.100	Unit Dose Labeling for Solid and Liquid Oral Dosage Forms (CPG 7132b.10)
Sec. 430.200	Repacking of Drug Products - Testing/Examination Under CGMPs (CPG 7132.13)
Sub Chapter 440-448	NEW DRUGS
Sec. 446.100	Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or Other Manipulations (CPG 7132c.06)
Sub Chapter 450-457	OTC
Sec. 450.500	Tamper-Resistant Packaging Requirements for Certain Over-the-Counter (OTC) Human Drug Products (CPG 7132a.17)
Sec. 450.550	Control and Accountability of Labeling Associated with Tamper-Resistant Packaging of Over-the-Counter Drug Products (CPG 7132.14)
Sub Chapter 480	STABILITY/EXPIRATION

Sec. 480.100	Requirements for Expiration Dating and Stability Testing (CPG 7132a.04)
Sec. 480.200	Expiration Dating of Unit Dose Repackaged Drugs (CPG 7132b.11)
Sec. 480.300	Lack of Expiration Date of Stability Data (CPG 7132a.10)

ATTACHMENT C

EXTRACTION STUDIES

An extraction study of a packaging component typically involves exposing a sample of the component, often subdivided into small pieces to increase surface area, to an appropriate solvent system at elevated temperatures, followed by chemical analysis. The purpose of elevated temperature is to increase the rate of extraction, so that a short experimental time may simulate a longer exposure time at room temperature, or to maximize the amount of extractables obtained from a sample.

The methods employed to analyze the resulting extracts vary, depending on the purpose of the extraction study and the nature of the packaging component. The extraction solvent may be evaporated to concentrate the extracts or to determine the total weight of nonvolatile extractables. Appropriate methods, such as HPLC or gas chromatography, may be used to obtain qualitative or quantitative extraction profiles of volatile or nonvolatile extractables.

Extraction studies may be conducted during the qualification of packaging components for any of the following purposes:

- To perform USP characterization tests on plastics (USP <661>) or elastomers (USP <381>)
- To perform USP Biological Reactivity Tests (USP <87> and <88>) on plastics or elastomers
- To obtain qualitative extraction profiles of plastics or elastomers
- To obtain quantitative extraction profiles of plastics or elastomers
- To evaluate whether the FDA indirect food additive regulations provide an adequate indicator of safety

Extraction studies may also be conducted on a routine basis as a quality control measure to monitor the chemical compositions of elastomeric or other packaging components.

The solvent that should be used in an extraction study depends on the purpose of the study. The ideal situation is for the extracting solvent to have the same propensity to extract substances as the dosage form, thus obtaining the same quantitative extraction profile. For this study, the preferred solvent would be the drug product or placebo vehicle. When feasible, the dosage form itself would be used. A stronger extracting solvent than the drug product would be used to obtain a qualitative extraction profile that would be used to establish quality control criteria.

ATTACHMENT D

ABBREVIATIONS

AAO	American Academy of Ophthalmology
ANDA	Abbreviated New Drug Application
BLA	Biologics License Application
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CGMP	Current Good Manufacturing Practice
CMC	Chemistry, Manufacturing, and Control
COA	Certificate of Analysis
CPSC	Consumer Product Safety Commission
DMF	Drug Master File
DPI	Dry Powder Inhaler
FDA	U.S. Food and Drug Administration (the Agency)
HDPE	High Density Polyethylene
IND	Investigational New Drug Application
LDPE	Low Density Polyethylene
LOA	Letter of Authorization
LVP	Large-Volume Parenteral
MDI	Metered Dose Inhaler
NDA	New Drug Application
PET	Polyethylene Terephthalate
PETG	Polyethylene Terephthalate G
PP	Polypropylene
PVC	Polyvinyl Chloride
QA	Quality Assurance
QC	Quality Control
SVP	Small-Volume Parenteral
USP/NF	U.S. Pharmacopeia/National Formulary

ATTACHMENT E

REFERENCES[27]

Center for Drug Evaluation and Research (CDER) Compressed Medical Gases Guideline (February 1989)

FDA *Guideline for Drug Master Files* (September 1989)

FDA *Guidance for Industry on the Submission of Documentation for the Sterilization Process Validation in Applications for Human and Veterinary Drug Products* (November 1994)

FDA *Guidance for Industry on the Content and Format on Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well Characterized, Therapeutic, Biotechnology-Derived Products* (November 1995)

FDA *Guidance for Industry on the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use* (August 1996)

FDA *Guidance for Industry on the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products* (January 1997)

FDA *Guidance for the Photostability Testing of New Drug Substance and Products* (May 1997)

FDA *Guidance for Industry on the Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances* (January 1998)

FDA *Guidance for Industry on the Content and Format of Chemistry, Manufacturing, and Controls and Establishment Description Information for a Vaccine or Related Product* (January 1999)

FDA *Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls and Establishment Description Information for Human Plasma-Derived Biological Product or Animal Plasma or Serum-Derived Products* (February 1999)

FDA *Guidance for Industry on the Content and Format of Chemistry, Manufacturing, and*

[27] A list of CDER and CBER guidances and guidelines is provided on the Internet at www.fda.gov/cder/guidances.index.htm and www.fda.gov/cber/guidelines.htm, respectively.

Controls and Establishment Description Information for a Biological In Vitro Diagnostic Product (March 1999)

FDA *Guidance for Industry on the Content and Format of Chemistry, Manufacturing, and Controls and Establishment Description Information for Allergenic Extract or Allergen Patch Test* (April 1999)

FDA *Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the FDA Form 356h, Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use* (May 1999)

出発原料、原材料、容器・施栓系記載の品質保証への役割

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容器・施栓:　須藤　盛皓、能登　州弘　(大協精工)

承認書の機能

- 製品の品質保証の最重要文書(規制当局と製造者の合意事項)
- 製品標準書が適切に書かれているかの判断における起点文書(行政側)
- 変更管理における最重要事項の記述(企業側)
- 製造方法に関して必要なことは承認書に記載