

DATES: Submit written or electronic comments on this list and on agency guidance documents at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: For general information regarding FDA's GGP's contact: Diane Sullivan-Ford, Office of Policy (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3480. For information regarding specific topics or guidance, please see contact persons listed in the table in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of September 19, 2000 (65 FR 56468), FDA published a final rule announcing its GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publishing an annual guidance document agenda of possible guidance topics or documents for development or revision during the coming year. The agency also committed to soliciting public input regarding these and additional ideas for

new topics or revisions to existing guidance documents (65 FR 56468 at 56477, 21 CFR 10.115(f)(5)).

The agency is neither bound by this list of possible topics nor required to issue every guidance document on this list or precluded from issuing guidance documents not on the list set forth in this document.

The following list of guidance topics or documents represents possible new topics or revisions to existing guidance documents that the agency is considering. The agency solicits comments on the topics listed in this document and also seeks additional ideas from the public.

The guidance topic or documents are organized by the issuing center or office within FDA and are further grouped by topic categories. The agency's contact persons are listed for each guidance in the following table.

TITLE/TOPIC OF GUIDANCE	CONTACT
I. CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)	
CATEGORY—COMPLIANCE AND INSPECTION	
Guidance for Industry: Reprocessing, Reworking and Blending of Biological Drug Substances and Drug Products	Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210
Guidance for Industry: Process Validation Considerations for Biological Drug Substances and Biological Drug Products	Same as above (Do)
Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing	Do
Guidance for Industry: Design, Installation and Operation of Heating, Ventilation and Air Conditioning (HVAC) Systems Used in the Manufacture of Products Regulated by the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research	Do
Guidance for Industry: Content and Format of the Warnings/Precautions Section of Labeling for Drugs and Biologics	Do
Guidance for Industry: Content and Format of the Pregnancy and Lactation Sections of Labeling for Drugs and Biologics	Do
Guidance for Industry and Reviewers: Measuring Patient Reported Outcomes to Support Medical Product Claims in Labeling and Advertising	Do
Compliance Program 7341.001 Inspections of Licensed Therapeutic Drug Products	Do
Compliance Program 7341.002—Inspection of Tissue Establishments	Do
Compliance Program 7342.001—Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors	Do
Compliance Program 7342.002—Inspection of Source Plasma Establishments	Do
Compliance Program 7342.006—Inspection of Plasma Derivatives of Human Origin	Do
Compliance Program 7342.008—Inspections of Licensed Viral Marker Test Kits	Do