Bulk Drug Substance Lists
Requirements for Bulk Drug Substances Used to Compound Under 503A

• Bulk drug substances (i.e., active ingredients) used to compound must be:
  – components of FDA-approved drugs;
  – the subject of a USP or NF monograph; or
  – on a list of bulk drugs developed by FDA of bulk drug substances acceptable for compounding

• In addition:
  – bulk must be made at an FDA-registered facility; and
  – be accompanied by a Certificate of Analysis (COA)
Outsourcing Facility Use of Bulk Drug Substances

• An outsourcing facility may not compound from bulk drug substances
  – unless the drug it is compounding appears on the FDA drug shortage list, or
  – the bulk drug substance appears on an FDA list identifying bulk drug substances for which there is a clinical need
Bulk Drug Substances Used by Outsourcing Facilities

• Bulk drug substances and other ingredients used to compound must comply with USP or NF monographs, if they exist

• Bulk drug substances must come from facilities that have registered with FDA and be accompanied by a certificate of analysis
FDA Solicited Nominations for Lists

• List of bulk drug substances that may be used to compound under section 503A; nomination period later reopened

• List of bulk drug substances that may be used to compound under section 503B (based on clinical need); nomination period later reopened

• List of drugs that cannot be compounded under sections 503A or 503B because they are difficult to compound
Status of Bulk Drug Lists

• We are evaluating the nominated substances for which adequate information was submitted to support the nominations
  – About 65 substances for 503A list
  – About 190 substances for 503B list
• Presented first 6 substances for 503A list to Pharmacy Compounding Advisory Committee in February – background package on the Web
• Continuing to evaluate nominated substances
Other Policy Documents in Development

- Final Interim Guidance on CGMPs for Outsourcing Facilities, and proposed regulations on CGMPs for outsourcing facilities
- General regulations implementing 503A and 503B
- Animal drug compounding guidance
- Radiopharmaceutical drug compounding