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