

*Contains Nonbinding Recommendations*

**APPENDIX B:  
HOW FDA INTENDS TO DETERMINE WHETHER A COMPOUNDED DRUG PRODUCT IS ESSENTIALLY A COPY OF  
A COVERED OTC DRUG UNDER SECTION 503B**

Section 503B(d)(2)(A)

**(1) Identical or Nearly Identical**

Is the compounded drug identical or nearly identical to a covered OTC drug? I.e., does the compounded drug product have the same . . .

- Active ingredient(s);
- Route of administration;
- Strength;
- Dosage form; and
- Excipient(s)

. . . as a covered OTC drug?

Yes →

**Essentially a Copy**  
*Drug may not be compounded under section 503B*

No ↓

**(2) Bulk Drug Substance**

Is a component of the compounded drug product a bulk drug substance that is also a component of a covered OTC drug?

Yes →

**Essentially a Copy**  
*Drug may not be compounded under section 503B of the FD&C Act*

No ↓

**Not Essentially a Copy**  
*May be compounded under section 503B (provided all conditions of section 503B are met)*

Section 503B(d)(2)(B)

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APPENDICES A & B

