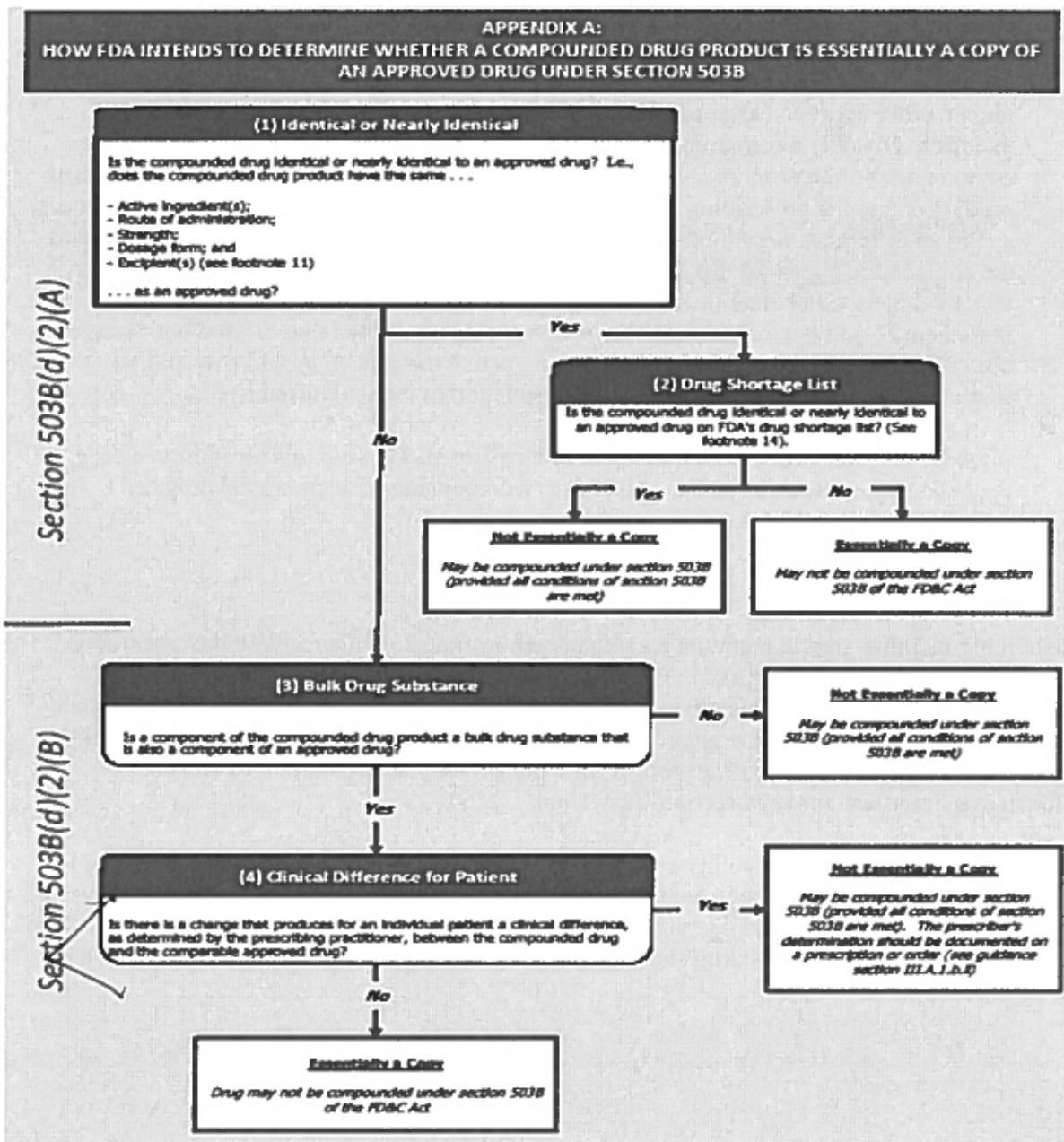


*Contains Nonbinding Recommendations**Draft — Not for Implementation*

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APPENDICES A & B461
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Contains Nonbinding Recommendations

Draft — Not for Implementation

**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)

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

