Draft Guidance on Colesevelam Hydrochloride

> This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Colesevelam Hydrochloride

Form/Route: Tablets/Oral

Recommended studies: 3 studies

1.   Type of study: *In-vitro* Equilibrium Binding Study
Design: *In-vitro*
Strength: 625 mg
Subjects: Not Applicable
Additional Comments: For additional information regarding the in-vitro studies recommended refer to the Guidance for Industry: *Cholestyramine Powder In Vitro Bioequivalence* in CDER's guidance page (under Biopharmaceutics)

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2.   Type of study: *In-vitro* Kinetic Binding Study
Design: *In-vitro*
Strength: 625 mg
Subjects: Not Applicable
Additional comments: See comments above

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3.   Type of study: I*n-vitro* Bridging Study
Design: *In-vitro*
Strength: 625 mg
Subjects: Not Applicable
Additional comments: A bridging study should be conducted to demonstrate that comparable equilibrium binding results can be attained in a side-by-side comparison of the whole tablets versus ground tablets.

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Analytes to measure: *In-vitro* bile acid salts binding

Bioequivalence based on (90% CI): k_2 (capacity constant)

Waiver request of in-vivo testing: Not Applicable

Dissolution test method and sampling times:

There is no USP method or FDA recommended dissolution method for this product it is virtually water-insoluble. Please develop a disintegration testing method to establish disintegration specifications for the product. For the method development, the disintegration rates of the test and reference products should be determined in various media, such as, deionized water, simulated gastric fluid, and simulated intestinal fluid.