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Draft Guidance on Sodium Iodide I-131

November 2021

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

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This is a new draft product-specific guidance for industry on generic sodium iodide I-131.

Active Ingredient: Sodium iodide I-131

Dosage Form; Route: Capsule; oral

Recommended Study: Request for waiver of in vivo bioequivalence study

Sodium Iodide I-131 capsule is a DESI[1] effective drug for which there are no known or suspected bioequivalence problems.

Analyte to measure: Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: 0.8 to 100 mCi capsule of the test product under 21 CFR § 320.22 (c)

[1] Drug Efficacy Study Implementation

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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