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≥1] As Determined By An FDA ≥1%] As Determined By An FDA ... Determined By An FDA-approved Test, That Have Progressed Following Prior Treatment And Who Have No Satisfactory Alternative Treatment Options. 1 (1.16, 2.1) Limitations Of Use: The Safety And Effectiveness Of Jan 17th, 2024 FDA's Overview Of - US FDA Small Business & Industry ... FDA Expectations Of Industry "Manufacturers Are Responsible For Understanding Their Processes, Which Includes

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