

FDA CONSOLIDATED CITIZEN PETITION RESPONSE REFERENCE:

- 06/1999 FDA draft guidance, Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action
- 04/2003 FDA, Statistical Information from the June 1999 Draft Guidance and the Statistical Information for In Vitro Bioequivalence Data Posted on August 18, 1999
- 04/2003 FDA draft guidance, Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action
- 04/2003 FDA, Statistical Information from the June 1999 Draft Guidance and the Statistical Information for In Vitro Bioequivalence Data Posted on August 18, 1999
- 07/2002 FDA guidance, Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry, Manufacturing, and Controls Documentation
- 07/2002 FDA guidance, Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry, Manufacturing, and Controls Documentation
- 06/1995 FDA guidance, Topical Dermatologic Corticosteroids: In Vivo Bioequivalence
- 11/02/2001 Cheng, Y.S., et al., "Characterization of Nasal Spray Pumps and Deposition Pattern in a Replica of the Human Nasal Airway," Journal of Aerosol Medicine, 14(2):267-80, 2001
- Dighe, S.V., and W.P. Adams, "Bioequivalence: A United States Regulatory Perspective," in Pharmaceutical Bioequivalence (P.G. Welling et al., eds.), 1991, pp. 347-380.
- 04/28/2004 Daley-Yates et al., "Bioavailability of Fluticasone Propionate and Mometasone Furoate Aqueous Nasal Sprays," European Journal of Clinical Pharmacology, 60(4):265-268, 2004).
- 2006 USP Monographs: Fluticasone Propionate
- 04/2000 FDA draft guidance, Allergic Rhinitis: Clinical Development Programs for Drug Products

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