

N115 FDA SUBMISSIONS

Until now the primary treatment for asthmatic bronchitis and chronic obstructive pulmonary diseases is the use of corticosteroids (67%). It is well documented that prolonged use of corticosteroids for the treatment of pulmonary diseases has serious side effects, including death. Other marketed drugs for the treatment of pulmonary diseases can produce central nervous system, cardiovascular, respiratory and gastrointestinal problems.

FDA Safety Submissions: Clinical Findings for N115

1. Rat Study: Effect of Intratracheal Injection of a Single Dose of Sodium pyruvate on the Lungs
2. Rabbit Study: Effect of a Single Dose and Multiple Doses of Inhaled Sodium Pyruvate on the Lungs
3. Rat Study: Effect of Multiple Intratracheal Administrations of Sodium Pyruvate on Lung Injury Caused by Bleomycin
4. Rat Study: Multiple Dose Toxicity Study of Aerosolized Sodium Pyruvate in Sprague-Dawley Rats
5. Rat Study: 180-Day Nose-Only Inhalation Study of Sodium Pyruvate in Charles River Rats
6. Rat Study: Sodium Pyruvate: A 90 Day and 80 Day Nose-Only Inhalation Study in Rats (Study 2). Dosing at 10X the human therapeutic dose
7. Two-week Rabbit Inhalation Study - Safety of Repeated Dosing at Different Sodium Pyruvate Concentrations. Maximum tolerated dosing at 200X the human therapeutic dose

Human Clinical Studies

In all clinical studies, the inhalation of sodium pyruvate demonstrated clinically significant improvements in all lung functions parameters including FEV-1, PEF, SaO₂ levels FEV-1/FVC ratios and clinically significant reductions in inflammatory cytokines, and hydrogen peroxide.

1. Inhaled Sodium Pyruvate for the Treatment of Bronchial Asthma/COPD, a Phase I/II Study.⁵ (John Votto, D.O., and Roger Thrall, Ph.D., Hospital for Special Care and the University of Connecticut Health Center)
2. Sodium Pyruvate/Nitric Oxide Pilot Study in Subjects with Lung Disease (John Votto, D.O., and Roger Thrall, Ph.D., Hospital for Special Care and the University of Connecticut Health Center)
3. Inhaled Sodium Pyruvate-SaO₂ Pilot Study in Subjects with Lung Disease. Final Report for COPD Subjects (John Votto, M.D., Hospital for Special Care and the University of Connecticut)
4. Long-Term Use of Inhaled Sodium Pyruvate for the Treatment of Chronic Obstructive Pulmonary Disease. This was a two-center study. (John Votto, M.D., Hospital for Special Care and the University of Connecticut Health Center, and Roger S. Thrall, Ph.D. Hospital for Special Care, and Geoffrey Chupp, MD, Yale University School of Medicine, Yale New Haven Hospital, New Haven, Connecticut.¹³
5. Use of Inhaled Sodium Pyruvate for the Treatment of Subjects with Cystic Fibrosis (Carlos Milla, M.D. The Minnesota Cystic Fibrosis Center. University of Minnesota Medical School. Minneapolis, Minnesota 55455.)¹⁴¹⁵,
6. Sodium Pyruvate Bronchodilation in Asthmatics (Donald Tashkin, M.D. David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA 90095)¹⁶¹⁷¹⁸
7. A Phase 1 Pilot Study on the Effect of Inhaled Sodium Pyruvate in Subjects with Chronic Obstructive Pulmonary Disease. (A non-IND study) Francisco Flores Murrieta, MD, and Héctor León Molina, MD. Instituto Nacional de Enfermedades Respiratorias, Mexico City, Mexico

8. Open Label, Three-Week Study on the Effects of the Addition of Sodium Pyruvate Inhalation Therapy to Standard Treatment in Patients with Pulmonary Fibrosis. (Mario Hernandez, M.D., Manuel Lam, M.D., Omar Lopez, R.N. Nova Research Institute, Miami, Florida 33125)
9. Results of an Open Label Study on the Acute Effects of Three Days Administration of Sodium Pyruvate Nasal Spray Inhalation Drug on Patients with Pulmonary Fibrosis. (Mario Hernandez, M.D., Manuel Lam, M.D., Omar Lopez, R.N. Nova Research Institute, Miami, Florida 33125)