

**Table of Contents to References for the Proposed Rule  
on  
Use of Ozone-Depleting Substances; Removal of Essential-Use Designation  
(Epinephrine)**

1. National Center for Health Statistics, “Early Release of Selected Estimates Based on Data From the 2005 National Health Interview Survey,” figure 15.4, available at [http://www.cdc.gov/nchs/data/nhis/earlyrelease/200606\\_15.pdf](http://www.cdc.gov/nchs/data/nhis/earlyrelease/200606_15.pdf).  
[pdf](#).

2. Alkermes, Inc., press release, dated March 22, 2004, available at <http://www.alkermes.com/newsroom/showArticle.aspx?id=267>.

3. Fu, K. et al., “Air<sup>®</sup>-Epinephrine: Inhalation Therapy for the Emergency Self-Treatment of Anaphylaxis,” Journal of Aerosol Medicine, Vol. 16(2):190, June 2003.

4. Hendeles, L. et al., “Response to Nonprescription Epinephrine Inhaler During Nocturnal Asthma,” Annals of Allergy, Asthma, and Immunology, 95:530, December 2005.

5. National Heart, Lung, and Blood Institute, “Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma,” NIH publication No. 97-4051, July 1997.

6. National Heart, Lung, and Blood Institute, “Expert Panel Report: Update on Selected Topics 2002: Guidelines for the Diagnosis and Management of Asthma,” NIH publication No. 02-5074, June 2003.

7. National Asthma Council Australia Ltd., “Asthma Management Handbook: 2002,” Melbourne:2002.

8. Boulet, J. P. et al., “Canadian Asthma Consensus Report, 1999,” Canadian

Medical Association Journal, 161(11 Supp.):S1, November 30, 1999.

9. Dickinson, B. D. et al., “Safety of Over-the-Counter Inhalers for Asthma: Report of the Council on Scientific Affairs,” Chest, 118(2):522, August 2000.

10. Cohen, R. A. and M. E. Martinez, “Health Insurance Coverage: Estimates from the National Health Interview Survey, 2005,” National Center for Health Statistics, June 2006, available at <http://www.cdc.gov/nchs/data/nhis/earlyrelease/insur200606.pdf>.

11. U.S. Census Bureau, “Table HI01. Health Insurance Coverage Status and Type of Coverage by Selected Characteristics: 2004: All Races,” available at [http://pubdb3.census.gov/macro/032005/health/h01\\_001.htm](http://pubdb3.census.gov/macro/032005/health/h01_001.htm).

12. National Center for Health Statistics, “Asthma Prevalence, Health Care Use and Mortality, 2002,” fig. 1. Available at <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/asthma/asthma.htm>.

13. Agency for Health Quality and Research, 2005 National Healthcare Disparities Report, AHQR publication 06-0017, December 2005, available at <http://www.ahrq.gov/qual/nhdr05/nhdr05.htm>.

14. Crain, E. F. et al., “Reported Difficulties in Access to Quality Care for Children with Asthma in the Inner City,” Archives of Pediatric and Adolescent Medicine,” 152:333, April 1998

15. Evans, R. et al., “A Randomized Clinical Trial to Reduce Asthma Morbidity Among Inner-City Children: Results of the National Cooperative Inner-City Asthma Study,” Journal of Pediatrics, 135(3):332, September 1999.

16. Bauman, L. J. et al., “Relationship of Adherence to Pediatric Asthma Morbidity Among Inner-City Children,” Pediatrics, 110(1):1, June 2006.

17. Bender, B. et al. "Measurement of Children's Asthma Medication Adherence by Self Report, Mother Report, Canister Weight, and Doser CT," Annals of Allergy, Asthma, and Immunology, 85:416, November 2000.
18. Erickson S. R. et al., "Compliance From Self-Reported versus Pharmacy Claims Data With Metered-Dose Inhalers," The Annals of Pharmacotherapy, 35(9): 997, September 2001.
19. Joyce, D. P., K. R. Chapman, and S. Kesten, "Prior Diagnosis and Treatment of Patients with Normal Results of Methocholine Challenge and Unexplained Respiratory Symptoms," Chest, 109(3):697, March 1996.
20. Kuschner, W. G. et al. "Nonprescription Bronchodilator Medication Use in Asthma," Chest, 112(4):987, October 1997.
21. Gibson, P., "Association Between Availability of Non-Prescription  $\beta_2$  Agonist Inhalers and Undertreatment of Asthma," British Medical Journal, 306:1514, June 5, 1993.
22. Giraud, V., and N. Roche, "Misuse of Corticosteroid Metered-Dose Inhaler Is Associated With Decreased Asthma Stability," European Respiratory Journal, 19:246, 2002.
23. Scarfone, R. J. et al., "Demonstrated Use of Metered-Dose Inhalers and Peak Flow Meters by Children and Adolescents with Acute Exacerbations," Archives of Pediatric and Adolescent Medicine, 156:378, April 2002.
24. Williams, M. V., "Inadequate Literacy Is a Barrier to Asthma Knowledge and Self-Care," Chest, 114(4):1008, October 1998.
25. Cloutier, M. et al., "Use of Asthma Guidelines by Primary Care Providers to

Reduce Hospitalizations and Emergency Department Visits in Poor, Minority, Urban Children,” Journal of Pediatrics, 146:591, May 2005.

26. Overbeek, S. E. et al., “Is Delayed Introduction of Inhaled Corticosteroids Harmful in Patients With Obstructive Airways Disease (Asthma and COPD)?” Chest, 110(1):35, July 1996.

27. Selroos, O. et al., “Effect of Early vs Late Intervention With Inhaled Corticosteroids in Asthma,” Chest, 108(5):1228, November 1995.

28. Salpeter, S. R., T. M. Ormiston, and E. E. Salpeter, “Meta-Analysis: Respiratory Tolerance to Regular  $\beta_2$  Agonist Use in Patients with Asthma,” Annals of Internal Medicine, 140(10):802, May 18, 2004.

29. Szeffler, S. et al., “Long-Term Effects of Budesonide or Nedocromil in Children With Asthma,” New England Journal of Medicine, 343:1054, October 12, 2000.

30. Guilbert, T. et al., “Long-Term Inhaled Corticosteroids in Pre-School Children at High Risk for Asthma,” New England Journal of Medicine, 354:1985, May 11, 2006.

31. Bisgaard, H. et al., “Intermittent Inhaled Corticosteroids in Infants with Episodic Wheezing,” New England Journal of Medicine, 354:1998, May 11, 2006.

32. Bousquet, J. et al., “Asthma: From Bronchoconstriction to Airways Inflammation and Remodeling,” American Journal of Respiratory and Critical Care Medicine, 161:1720, 2000.

33. United Nations Environmental Programme, 2006 Assessment Report of the Technology and Economic Assessment Panel, 2006.

34. United Nations Environmental Programme, Production and Consumption of

Ozone-Depleting Substances: 1986-2004, 2005.

35. U.S. Environmental Protection Agency, “The Benefits and Costs of the Clean Air Act: 1990–2010,” (<http://www.epa.gov/air/sect812/copy99.html>) November 1999.

36. National Center for Health Statistics, “Early Release of Selected Estimates Based on Data From the January-September 2006 National Health Interview Survey” March 28, 2007, available at <http://www.cdc.gov/nchs/about/major/nhis/released200703.htm#15>.

37. American Lung Association, “Trends in Asthma Morbidity and Mortality,” Epidemiology & Statistics Unit, Research and Scientific Affairs, July 2006.

38. Blanc, P. D. et al., “Use of Herbal Products, Coffee or Black Tea, and Over-the-Counter Medications as Self-Treatments Among Adults with Asthma,” Journal of Allergy and Clinical Immunology, 100:(6\1) 789, December 1997.

39. Mannino, D. M. et al., “Surveillance for Asthma—United States, 1980-1999,” Morbidity and Mortality Weekly Report, 51(SS01):1-13, March 29, 2002.

40. Analysis completed by FDA based on retail sales data from drug stores and supermarkets provided by ACNielsen for the 52 weeks ending September 9, 2006.

41. U.S. Environmental Protection Agency, final rule, “Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2006,” 71 FR 58504, October 4, 2006.

42. Rozek, R. P., and E. R. Bishko, “Economics Issues Raised in the FDA’s Proposed Rule on Removing the Essential-Use Designation for Albuterol MDIs,” National Economic Research Associates, August 13, 2004 (FDA Docket No. 2003P–0029/C25).

43. Analysis completed by FDA based on prescription data provided by IMS Health, National Prescription Audit, 2004; IMS Health, IMS MIDAS (TM), Q1/2004–Q2/2004.
44. Gal, A., and N. R. Chari, “TEVA, SEPR: SGP to Phase Out CFC Albuterol Production by Early 2007; TEVA and SEPR Likely to Benefit,” report prepared for Sanford C. Bernstein & Co., LLC (New York), October 17, 2006.
45. Berger, W. E. et al., “The Utility of the Health Plan Employer Data and Information Set (HEDIS) Asthma Measure to Predict Asthma-Related Outcomes,” Annals of Allergy, Asthma and Immunology, 93:538, December 2004.
46. Centers for Medicare and Medicaid Services, Medicaid at-a-Glance 2005: A Medicaid Information Source, available at <http://www.cms.hhs.gov/MedicaidEligibility/downloads/MedGlance05.pdf>.
47. Department of Health and Human Services, notice, “Annual Update of the HHS Poverty Guidelines,” 71 FR 3848, January 24, 2006.