

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule does not require information collections subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (Public Law 104-13). FDA received no comments on its determination concerning information collections.

FDA is amending its labeling regulations to require that the labeling for systemic antibacterial drug products include certain statements, specified by FDA, about the link between unnecessary use of antibiotics and the development of drug-resistant bacterial strains. These labeling statements are not subject to review by OMB because they are "originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)) and therefore do not constitute a "collection of information" under the PRA of 1995.

Holders of approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs) are required to submit supplements and holders of pending NDAs and ANDAs are required to submit amendments to comply with the new labeling requirements. The final rule also requires that all new NDAs and ANDAs for systemic antibacterial drug products comply with the new labeling requirements. FDA regulations governing the submission and approval of NDAs and ANDAs, including the submission of product labeling, are in part 314 (21 CFR part 314). Recordkeeping and reporting requirements included in part 314 are approved by OMB until March 31, 2005, under OMB control number 0910-0001.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**)

and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

- Centers for Disease Control, and American Academy of Pediatrics, edited by S. F. Dowell, "Principles of Judicious Use of Antimicrobial Agents for Pediatric Upper Respiratory Tract Infections," Supplement to *Pediatrics*, vol. 101, pp. 163-164, January 1998.
- McCaig, L. F., R. E. Besser, and J. M. Hughes, "Trends in Antimicrobial Prescribing Rates for Children and Adolescents," *Journal of the American Medical Association*, vol. 287, pp. 3096-3102, 2002.
- Perz, J. F. et al., "Changes in Antibiotic Prescribing for Children After a Community-Wide Campaign," *Journal of the American Medical Association*, vol. 287, pp. 3103-3109, 2002.
- Pichichero, M. E., "Dynamics of Antibiotic Prescribing for Children," *Journal of the American Medical Association*, vol. 287, pp. 3133-3135, 2002.
- Interagency Task Force on Antimicrobial Resistance, *A Public Health Action Plan to Combat Antimicrobial Resistance Part 1: Domestic Issues*, 2001, available at <http://www.cdc.gov/drugresistance/actionplan/html/index.htm>.
- Gonzales, R. D. et al., "Infections Due to Vancomycin-Resistant *Enterococcus Faecium* Resistant to Linezolid," *Lancet*, vol. 357, p. 1179, 2001.
- Ibrahim, E. H. et al., "The Influence of Inadequate Antimicrobial Treatment of Bloodstream Infections on Patient Outcomes in the ICU Setting," *Chest*, vol. 118, pp. 146-155, 2000.
- Holmberg S. D. et al., "Health and Economic Impacts of Antimicrobial Resistance," *Review of Infectious Disease*, vol. 9, pp. 1065-1078, 1987.
- Singh, N. et al., "Methicillin-Resistant *Staphylococcus Aureus*: The Other Emerging Resistant Gram-Positive Coccus Among Liver Transplant Recipients," *Clinical Infectious Diseases*, vol. 30, pp. 322-327, 2000.
- Chaix, C. et al., "Control of Endemic Methicillin-Resistant *Staphylococcus Aureus*: A Cost-Benefit Analysis in an Intensive Care Unit," *Journal of the American Medical Association*, vol. 282, pp. 1745-1751, 1999.
- Rubin, R. J. et al., "The Economic Impact of *Staphylococcus Aureus* Infection in New York City Hospitals," *Emerging Infectious Diseases*, vol. 5, pp. 9-17, 1999.
- Abramson, M. A., and D. J. Sexton, "Nosocomial Methicillin-Resistant and Methicillin-Susceptible *Staphylococcus Aureus* Primary Bacteremia: At What Costs?" *Infection Control and Hospital Epidemiology*, vol. 20, pp. 408-411, 1999.
- Carmeli, Y. et al., "Health and Economic Outcomes of Antibiotic Resistance in *Pseudomonas Aeruginosa*," *Archives of Internal Medicine*, vol. 159, pp. 1127-1132, 1999.
- Graves, E. J., and B. S. Gillum, "Detailed Diagnoses and Procedures, National Hospital Discharge Survey, 1995," National Center for Health Statistics Vital Health Statistics Series 13 (130):115, 1997.
- Owings, M. F., and L. Lawrence, "Detailed Diagnoses and Procedures, National Hospital Discharge Survey, 1997," National Center for Health Statistics Vital Health Statistics Series 13 (145):118, 1999.
- HCUPnet, Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality, Rockville, MD (<http://www.ahrq.gov/data/hcup/hcupnet.htm>).
- U.S. General Accounting Office Report, "Antimicrobial Resistance: Data to Assess Public Health Threat From Resistant Bacteria Are Limited," GAO/HEHS/NSIAD/RCED-99-132, pp. 5-6, April 1999.
- Centers for Disease Control, *Active Bacterial Core Surveillance (ABCs) Report; Emerging Infections Program Network, Streptococcus Pneumoniae*, 1999 (<http://www.cdc.gov/ncidod/dbmd/abc>).
- Feikin, D. R. et al., "Mortality From Invasive Pneumococcal Pneumonia in the Era of Antibiotic Resistance, 1995-1997," *American Journal of Public Health*, vol. 90, pp. 223-229, 2000.
- Campbell, G. D., and R. Silberman, "Drug-Resistant *Streptococcus Pneumoniae*," *Clinical Infectious Diseases*, vol. 26, pp. 1188-1195, 1998.
- Danila, R. N. et al., "Addressing Emerging Infections: The Partnership Between Public Health and Primary Care Physicians," *Emerging Infections*, vol. 106, pp. 90-105, 1999.
- Castillo, E. M. et al., "*Streptococcus Pneumoniae*: Bacteremia in an Era of Penicillin Resistance," *American Journal of Infection Control*, vol. 28, pp. 239-243, 2000.
- Jacobs, M. R., "Drug-Resistant *Streptococcus Pneumoniae*: Rational Antibiotic Choices," *American Journal of Medicine*, vol. 106, pp. 19S-25S, 1999.
- World Health Organization, "Overcoming Antimicrobial Resistance," *WHO Report on Infectious Diseases 2000*, WHO/CDS/2000.2, Chapter 4, <http://www.who.int/infectious-disease-report/2000/>.
- Stosor, V. et al., "Enterococcus Faecium Bacteremia: Does Vancomycin Resistance Make a Difference?" *Archives of Internal Medicine*, vol. 158, pp. 522-527, 1998.
- Bhavnani, S. M. et al., "A Nationwide, Multicenter, Case-Control Study Comparing Risk Factors, Treatment, and Outcome for Vancomycin-Resistant and -Susceptible Enterococcal Bacteremia," *Diagnostic Microbiology and Infectious Disease*, vol. 36, pp. 145-158, 2000.
- Edmond, M. B. et al., "Vancomycin-Resistant Enterococcal Bacteremia: Natural History and Attributable Mortality," *Clinical Infectious Diseases*, vol. 23, pp. 1234-1239, 1996.
- Gleason, T. G. et al., "Prediction of Poorer Prognosis by Infection With Antibiotic-Resistant Gram-Positive Cocci Than by Infection With Antibiotic-Sensitive Strains," *Archives of Surgery*, vol. 134, pp. 1033-1040, 1999.
- Paladino, J. A., "Pharmacoeconomics of Antimicrobial Therapy," *American Journal of Health-System Pharmacy*, vol. 56, supp. 3, pp. S25-S28, 1999.
- Linden, P. K. et al., "Differences in Outcomes for Patients With Bacteremia Due to Vancomycin-Resistant *Enterococcus faecium* or Vancomycin-Susceptible *E.*