

By order of the Federal Open Market Committee, January 30, 2003.

Vincent R. Reinhart,

Secretary, Federal Open Market Committee.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 00N-1463]

RIN 0910-AB78

Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to require that the labeling for all systemic antibacterial drug products (i.e., antibiotics and their synthetic counterparts) intended for human use include certain statements about using antibiotics in a way that will reduce the development of drug-resistant bacterial strains. The final rule reflects a growing concern in FDA and the medical community that unnecessary use of systemic antibacterials has contributed to a dramatic increase in recent years in the prevalence of drug-resistant bacterial infections. The final rule is intended to encourage physicians to prescribe systemic antibacterial drugs only when clinically necessary. The final rule is also intended to encourage physicians to counsel their patients about the proper use of such drugs and the importance of taking them exactly as directed.

DATES: This rule is effective February 6, 2004.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

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I. Background

In the **Federal Register** of September 19, 2000 (65 FR 56511), FDA proposed to amend its regulations to require that the labeling for all systemic antibacterial drug products (i.e., antibiotics and their synthetic counterparts) intended for human use include certain statements about using antibiotics in a way that will reduce the development of drug-resistant bacterial strains. The new labeling is intended to help educate physicians and the public about the resistance problem and to encourage physicians to prescribe systemic antibacterial drugs only when clinically necessary. FDA personnel involved in drafting the statements included practicing physicians who are in a position to evaluate the effect of the labeling on physicians. The statements were also reviewed by other practicing physicians in the agency.

Antibacterial resistance among disease-causing bacteria represents a serious and growing public health problem in the United States and worldwide. Many bacterial species, including the species that cause pneumonia and other respiratory tract infections, meningitis, and sexually transmitted diseases, are becoming increasingly resistant to the antibacterial drugs used to treat them. Several bacterial species have developed strains that are resistant to every approved antibiotic, thus severely limiting the therapeutic options available for adequate treatment. The incidence of resistance in both hospital- and community-acquired infections has increased dramatically in the past several years, making many common illnesses more difficult to treat than they were only 5 or 10 years ago.

According to the Centers for Disease Control and Prevention (CDC), half of the 100 million antibiotic prescriptions

a year written by office-based physicians in the United States are unnecessary because they are prescribed for the common cold and other viral infections, against which antibiotics are not effective (Ref. 1). Unnecessary use of antibiotics in hospitals is common as well. The more an antibiotic is used, the more likely it is that bacteria will develop resistance to it. Thus, using antibiotics when they are not necessary contributes to the increasing prevalence of antibacterial resistance without providing any patient benefit.

Educating physicians and the public about the resistance problem and discouraging unnecessary use of antibiotics are important steps to decrease the prevalence of antibacterial resistance and slow its future development and spread. FDA believes that professional labeling has an important role in that educational effort. Therefore, FDA is requiring that the labeling for systemic antibacterial drug products include certain statements about unnecessary use of antibiotics and the link between such use and the emergence of drug-resistant bacterial strains.

Recent reports of a reduction in antibiotic prescribing raise the hope that the trend in overuse of antibiotics can be reversed and provide additional support for the need to include information in labeling to ensure the continued safety and efficacy of antibiotics (Refs. 2 and 3). The studies reported were conducted in children seen in outpatient practice and have not been confirmed in either adults or hospitalized patients. Nevertheless, as the authors of the two studies and the editorial (Ref. 4) that accompanied them note, efforts to promote the appropriate use of antibiotics have likely contributed to a decrease in antibiotic prescribing. These authors observe that it is important to continue such efforts if these gains are to be maintained. The authors cite the ongoing role of the U.S. Public Health Service Action Plan (Ref. 5) to combat antimicrobial resistance. FDA is one of the three lead agencies for this plan. The plan indicates that educational efforts should be one of the highest priorities and placing information on the labeling of systemic antimicrobial products is specifically cited in the plan.

II. Highlights of the Final Rule

The final rule amends FDA regulations to require that all systemic antibacterial drug products (i.e., antibiotics and their synthetic counterparts) intended for human use contain additional labeling information