



To define, to promote and to realize the prudent use of antibiotics around the world.
July 16, 1998

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Doctor Michael A. Friedman
Lead Deputy Director
Food and Drug Administration
5600 Fisher's Lane
Room 1471
Rockville, MD 20857

Dear Dr. Friedman:

The *Alliance for the Prudent Use of Antibiotics* (APUA) is a Boston based organization committed to defining and promoting the prudent use of antibiotics around the world. With more than 2,000 members in 90 countries, and 17 foreign affiliates and chapters, the APUA conducts research and educational programs in conjunction with concerned clinicians and microbiologists at the grass roots level. President of APUA Stuart Levy, MD, who is also president of the American Society of Microbiology, has been advocating judicious use of this vital medical resource since 1980.

It has come to our attention that the FDA is considering labeling new antibiotics in order to remind physicians prescribing antimicrobials of the standards of optimal use. With emerging reports of resistant organisms, including those resistant to vancomycin, the antibiotic of last resort, the APUA appreciates and encourages the FDA in its recent efforts to promote the judicious use of antibiotics. While we applaud the new labeling requirements explaining optimal use, we feel that only a more aggressive policy that applies to old as well as new antibiotics will achieve the desired effect. For example, the antibiotic ampicillin is an old antibiotic frequently used for treatment of persistent ear infections in the United States. We ask that the FDA apply the labeling requirement to all antibiotics. 'Grandfathering' is not appropriate when increasing resistance threatens the public health of U.S. citizens.

Existing antibiotics will remain effective treatments for bacterial infection if used properly. Since there are no new classes of antibiotics expected in the near future, preserving those in current use is essential. APUA recommends a comprehensive labeling policy for antibiotics to preserve this vital resource.

Sincerely,

Stuart B. Levy, MD
President, APUA

CC: Robert Temple, FDA-Center for Drug Evaluation and Research
Stephen Sundlof, FDA-Center for Veterinary Medicine

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