



Society Of Infectious Diseases Pharmacists

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November 30, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852.

Re: Docket Number 00N-1463 - Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use

To Whom It May Concern:

The aforementioned docket published in the Federal Register on September 19, 2000 (Volume 65, Number 182, Page 56511-56518), outlined a proposal by the Food and Drug Administration (FDA) which would require that all systemic antibacterial drug products (i.e., antibiotics and their synthetic counterparts) intended for human use contain additional labeling information about the emergence of drug-resistant bacterial strains. The proposal reflects a growing concern in FDA and the medical community that overprescription and inappropriate use of systemic antibacterials has contributed to a dramatic increase in recent years in the prevalence of drug-resistant bacterial infections. The proposal is intended to encourage physicians to prescribe systemic antibacterials more judiciously and only when clinically necessary, and to counsel their patients about the proper use of such drugs and the importance of taking them exactly as directed.

The Society of Infectious Diseases Pharmacists (SIDP) supports this proposal and urges the FDA to approve the proposed change in labeling information. However, we would like to suggest the following modifications to the proposed document:

(1) the proposed labeling should also be applied to otic, ophthalmic, and topical antimicrobial agents (both prescription and over-the-counter) intended for human use.

(2) the proposed labeling should also be applied to antimicrobial agents intended not only for the treatment of bacteria, but which are also used in the treatment of mycobacteria. [Examples of such antimicrobial agents could include clarithromycin, rifampin, and fluoroquinolones.]

The SIDP is committed to develop interdisciplinary statements on policy and guidelines for the rational use and evaluation of antimicrobial agents. As such, we appreciate the opportunity to respond to this important issue.

Sincerely,

Peggy L. Carver, Pharm.D.
President, SIDP

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00N-1463

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