



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Centers for Disease Control
and Prevention

December 1, 2000

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Woodmont Office Complex 2 (Mail Stop HFD-001)
1451 Rockville Pike
Rockville, Maryland 20852

re: Docket No. 00N-1463, Labeling Requirements for Systemic Antibacterial Drug Products
Intended for Human Use

Dear Dr. Woodcock:

On behalf of the National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC), I am writing to express strong support for the new labeling requirements for systemic antibacterial drug products intended for human use that were recently proposed by the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)

The need for these new requirements is well explained in the announcement proposing the rule (Federal Register September 19, 2000;65:56511-18). Labeling changes such as this are consistent with several action items to promote more appropriate antimicrobial use that are included in the draft Public Health Action Plan to Combat Antimicrobial Resistance (<http://www.cdc.gov/drugresistance/actionplan/index.htm>). This Plan, as you know, was developed by an Interagency Task Force on Antimicrobial Resistance, co-chaired by CDC, FDA, and the National Institutes of Health, and is now in the final stages of review. For the label change to have an impact, it will be important to ensure that all antimicrobial drug promotional and marketing activities, whether directed at clinicians, health care organizations, or the public, explicitly and thoroughly communicate the cautions expressed.

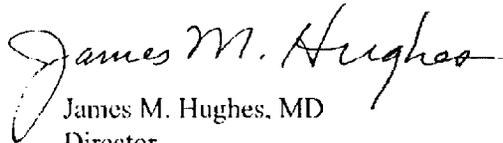
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Page 2 - Dr. Woodcock

I congratulate CDER on developing and proposing this important label change. My colleagues in NCID and I look forward to continued collaboration with CDER in activities to combat the emerging threat of antimicrobial resistance.

Sincerely

A handwritten signature in black ink that reads "James M. Hughes". The signature is written in a cursive style with a large, looping initial "J".

James M. Hughes, MD

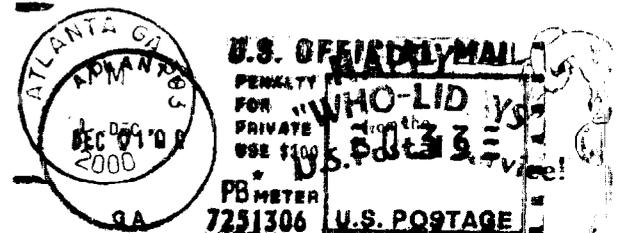
Director

National Center for Infectious Diseases

Dr. James M. Hughes
DEPARTMENT OF
HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL
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ATLANTA, GEORGIA 30333

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