


This MOU does not modify existing cooperative activities nor does it preclude entering into separate arrangements for special programs that can be handled more efficiently and expeditiously by special arrangements.

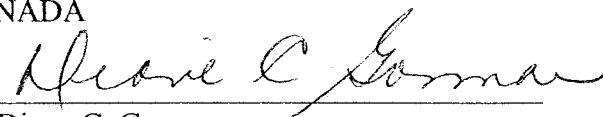
Nothing in this MOU is intended to diminish or otherwise affect the authority of either Participant to carry out its regulatory responsibilities and programs. In addition, no provision of this MOU restricts either Participant from conducting its own inspection of a therapeutic product manufacturing facility within the jurisdictional boundaries of the other country when needed to meet the needs of its own regulatory programs.

Signed at Ottawa, Canada on this eighteenth day of November 2003 in duplicate in the English language.

FOR THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA


Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

FOR THE HEALTH PRODUCTS AND FOOD BRANCH
HEALTH CANADA
OF CANADA


Diane C. Gorman,
Assistant Deputy Minister

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. 2003N-0539]

**Over-the-Counter Drug Products;
Safety and Efficacy Review**

AGENCY: Food and Drug Administration,
HHS

ACTION: Request for data and
information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call for data for certain categories of ingredients in over-the-counter (OTC) drug products that are eligible for the original OTC drug review but have not been reviewed by FDA to date. FDA will review the submitted data and information as part of its ongoing review of OTC drug products to determine whether these ingredients and products are generally recognized as safe and effective (GRAS/E) for their labeled uses. This document also requests the