

**CONFIDENTIALITY COMMITMENT  
STATEMENT OF LEGAL AUTHORITY  
AND COMMITMENT FROM  
THE IRISH NATIONAL ACCREDITATION BOARD  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION  
SHARED  
BY THE U. S. FOOD AND DRUG ADMINISTRATION (USFDA), U.S.  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

The United States Food and Drug Administration (USFDA), a part of the United States Department of Health and Human Services, is authorized under 21 C.F.R. § 20.89 ("Communications with Foreign Government Officials") to disclose non-public information to The Irish National Accreditation Board (INAB) regarding USFDA regulated products as part of cooperative law enforcement or cooperative regulatory activities. This sharing is in the interest of public health as it relates to the monitoring of nonclinical laboratories and nonclinical laboratory studies.

The INAB understands that some of the information it receives from USFDA may include non-public information exempt from public disclosure under the laws and regulations of the United States of America, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. The INAB understands that this non-public information is shared in confidence, and that USFDA considers it critical that the INAB maintain the confidentiality of the information. Public disclosure of this information by the INAB could seriously jeopardize any further scientific and regulatory interactions between USFDA and the INAB. US FDA will advise the INAB of the non-public status of the information at the time that the information is shared.

Therefore, the INAB certifies that it:

1. has the authority to protect the non-public information provided to the INAB in confidence by the USFDA from public disclosure;
2. will not publicly disclose the USFDA-provided non-public information without the written authorization of the owner of the information, the written authorization from the individual who is the subject of the personal privacy information, or a written statement from USFDA that the information no longer has non-public status;
3. will inform USFDA within two working days of any effort made to obtain USFDA-provided non-public information from the INAB by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of USFDA-provided non-public information, the INAB will take all measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and

- will promptly inform USFDA of any changes to Irish laws, the INAB policies or procedures that would affect the INAB ability to honor the agreements in this document.

Tom Dempsey  
Signature of the INAB official

14 June 2005  
Date

TOM DEMPSEY  
Print or Type name of the INAB official

MANAGER  
Title of the INAB official

The Irish National Accreditation Board  
Wilton Park House  
Wilton Place  
Dublin 2  
Ireland

Telephone and facsimile: + 353-1-6073181 TEL  
+ 353-1-6073109 FAX