

**STATEMENT OF AUTHORITY AND CONFIDENTIALITY COMMITMENT FROM THE  
UNITED STATES FOOD AND DRUG ADMINISTRATION NOT TO PUBLICLY  
DISCLOSE NON-PUBLIC INFORMATION SHARED BY THE AGÊNCIA NACIONAL DE  
VIGILÂNCIA SANITÁRIA OF BRAZIL**

The Agência Nacional de Vigilância Sanitária of Brazil (ANVISA) is authorized to disclose non-public information to the United States Food and Drug Administration (FDA) regarding ANVISA-regulated products as part of cooperative law enforcement or cooperative regulatory activities. ANVISA proposes to share non-public information regarding, among other things, the safety, effectiveness, or quality of ANVISA-regulated products with the FDA.

This Commitment is intended to strengthen communication between ANVISA and FDA to enhance their ability to protect and promote the health and safety of their respective populations with respect to products within the regulatory jurisdiction of ANVISA and FDA.

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

Therefore, FDA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to FDA in confidence by ANVISA;
2. will not publicly disclose such ANVISA-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 ANVISA that the information no longer has non-public status;
3. will inform ANVISA promptly of any effort made by judicial or legislative mandate to obtain ANVISA provided non-public information from FDA. If such judicial or legislative mandate orders disclosure of ANVISA-provided non-public information, FDA will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and
4. will promptly inform ANVISA of any changes to U.S. laws, or to any relevant policies or procedures, that would affect FDA's ability to honor the commitments in this document.

For the FDA:

Margaret A. Hamburg, M.D.

Commissioner of Food and Drugs

September 24, 2010