

# ATTACHMENT

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**U.S. Food and Drug Administration**



Department of Health and Human Services

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[Code of Federal Regulations]  
 [Title 21, Volume 7]  
 [Revised as of April 1, 2006]  
 [CITE: 21CFR601.50]

TITLE 21--FOOD AND DRUGS  
 CHAPTER I--FOOD AND DRUG ADMINISTRATION  
 DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 SUBCHAPTER F--BIOLOGICS

PART 601 -- LICENSING

Subpart F--Confidentiality of Information

Sec. 601.50 Confidentiality of data and information in an investigational new drug notice for a biological product.

(a) The existence of an IND notice for a biological product will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an IND file for a biological product shall be handled in accordance with the provisions established in 601.51.

(c) Notwithstanding the provisions of 601.51, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational biological product has been used a copy of any adverse reaction report relating to such use.

[39 FR 44656, Dec. 24, 1974]

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