

MODEL LETTER REQUESTING NON-PUBLIC INFORMATION  
(ON THE REQUESTER'S LETTERHEAD)

Director, Office of Policy and Risk Management, Office of Regulatory Affairs  
c/o Testimony Specialist

Food and Drug Administration  
12420 Parklawn Drive  
Element Bldg., Rm. 4042  
Rockville, Maryland 20857

Attention: Ms. Lauren DiPaola

Dear Ms. DiPaola:

The \_\_\_\_\_ (title of agency) would like the following non-public information pursuant to 21 C.F.R. § 20.88 (list the type of records/information requested, including the firm and/or product name(s))

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The purpose for which the information is requested is

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The records will only be used for the following authorized law enforcement activity: \_\_\_\_\_ (Also, indicate whether the request for information is the result of an ongoing investigation, and if it is, give the details.)

I certify that the law enforcement activity is authorized by law, that the records or information will be used only for the stated purposes and will not be further disclosed without the written permission of the Food and Drug Administration.

I understand that 21 U.S.C. § 331(j) of the Federal Food, Drug, and Cosmetic Act prohibits disclosure of trade secret information outside the Department of Health and Human Services.

If you have any questions, please contact me at: (indicate address, telephone number and facsimile number).

Sincerely,

Name and Title of Requester