



March 21, 2006

Via U.S. Mail

Food and Drug Administration Staff  
Division of Freedom of Information (DFOI)  
5600 Fishers Lane, Parklawn (PKLN) Building  
HFI-35, Room 6-30  
Rockville, MD 20857

***RE: Freedom of Information Act Request***

Dear FOI Staff Officer:

Pursuant to the Freedom of Information Act, I request:

A copy of the entire administrative record of the decision of the Office of Generic Drugs (OGD) (including, but not limited to, documents related to reference number: OGD #06-0200) that abbreviated new drug applications (ANDAs) or applications filed under 505(b)(2) for vancomycin hydrochloride capsules qualify for a waiver of *in vivo* bioequivalence and may demonstrate bioequivalence to the reference listed drug Vancocin® through *in vitro* dissolution testing.

I will gladly pay the charges for search time and photocopying. Search results should be sent to:

[personal information redacted]

Thank you for your consideration of this FOIA request.

Sincerely,

[personal information redacted]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

[personal information redacted]

03/27/2006

In Reply refer to:

2006-4517

Your reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

VANCOMYCIN HCL CAPS OGD #06-0200 - BIOEQUIVALENCE RECS

We will respond as soon as possible and may charge you a fee for processing your request. If you have any questions about your request, please call Shera S. Behram, Information Technician, at (301) 827-6552 or write to us at:

Food and Drug Administration  
Division of Freedom of Information  
5600 Fishers Lane, HFI-35  
Rockville, MD 20857

If you call or write, use the reference number above which will help us to answer your questions more quickly.