

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-154/S-032, S-033

20-155/S-023, S-024

20-156/S-024, S-025

ADMINISTRATIVE AND CORRESPONDENCE **DOCUMENTS**

PATENT INFORMATION

- 1) Patent No./Expiration: U.S. Patent 4,861,759; expires August 29, 2006
Type of Patent: Method of use
Patent Owner: United States of America represented by
Department of Human Services

- 2) Patent No./Expiration: U.S. Patent 5,254,539; expires August 29, 2006
Type of Patent: Method of use
Patent Owner: United States of America represented by
Department of Human Services

- 3) Patent No./Expiration: U.S. Patent 5,616,566; expires August 29, 2006
Type of Patent: Method of use
Patent Owner: United States of America represented by
Department of Human Services

- 4) Patent No./Expiration: U.S. Patent 5,880,106; expires July 22, 2011
Type of Patent: Composition
Patent Owner: Bristol-Myers Squibb Company

Bristol-Myers Squibb Company is the exclusive licensee of U.S. Patents 4,861,759, 5,254,539 and 5,616,566 by virtue of an agreement with NTIS dated February 1, 1988.

DECLARATION

The undersigned declares that U.S. Patents 4,861,759, 5,254,539, 5,616,566 and 5,880,106 cover the use of 2',3'-dideoxyinosine (ddI) which is the subject of the present Supplemental New Drug Application.

Samuel J. DuBoff

Signature of Authorized Person

Samuel J. DuBoff

Name of Authorized Person

Patent Counsel-International

Title of Authorized Person

April 13, 1995

Date

Appears This Way
On Original

Exclusivity Checklist

NDA: 20-154 S-032, S-033, 20-155, S-027, S-029, 20-156 S-021, 502			
Trade Name: Videx Chewable Tablets, Powder for Oral Soln, Pediatric Powder for Oral Soln.			
Generic Name: didanosine			
Applicant Name: Bristol-Myers Squibb			
Division: Division of Antiviral Drug Products			
Project Manager: Destry Sullivan			
Approval Date: July 24, 2000			
PART I: IS AN EXCLUSIVITY DETERMINATION NEEDED?			
1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete Parts II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.			
a. Is it an original NDA?	Yes	No	<input checked="" type="checkbox"/>
b. Is it an effectiveness supplement?	Yes	No	<input checked="" type="checkbox"/>
c. If yes, what type? (SE1, SE2, etc.)	SE8		
Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")	Yes	No	<input checked="" type="checkbox"/>
If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.			
Explanation:			
If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:			
Explanation:			
d. Did the applicant request exclusivity?	Yes	No	<input checked="" type="checkbox"/>
If the answer to (d) is "yes," how many years of exclusivity did the applicant request?			
IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS.			
2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use?	Yes	No	<input checked="" type="checkbox"/>
If yes, NDA # 20-154, 20-155, 20-156			
Drug Name: VIDEX			

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS.

3. Is this drug product or indication a DESI upgrade? Yes No

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS (even if a study was required for the upgrade).

PART II: FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2, as appropriate)

1. Single active ingredient product. Yes No

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

Yes		No	
Yes		No	

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

Drug Product	
NDA #	
Drug Product	
NDA #	
Drug Product	
NDA #	

2. Combination product. Yes No

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

Yes		No	
Yes		No	

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

Drug Product	
NDA #	
Drug Product	
NDA #	
Drug Product	

NDA #			
IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS. IF "YES," GO TO PART III.			
PART III: THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS			
To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2, was "yes."			
1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.	Yes	No	
IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS.			
2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application. For the purposes of this section, studies comparing two products with the same ingredient(s) are considered to be bioavailability studies			
a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?	Yes	No	
If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCKS.			
Basis for conclusion:			
b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?	Yes	No	
1) If the answer to 2 b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.	Yes	No	

If yes, explain:			
2) If the answer to 2 b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?	Yes		No
If yes, explain:			
c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:			
Investigation #1, Study #:			
Investigation #2, Study #:			
Investigation #3, Study #:			
3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.			
a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")			
Investigation #1	Yes		No
Investigation #2	Yes		No
Investigation #3	Yes		No
If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:			
Investigation #1 -- NDA Number			
Investigation #2 -- NDA Number			
Investigation #3 -- NDA Number			
b) For each investigation identified as "essential to the approval," does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?			
Investigation #1	Yes		No
Investigation #2	Yes		No
Investigation #3	Yes		No
If you have answered "yes" for one or more investigations, identify the NDA in which a similar investigation was relied on:			
Investigation #1 -- NDA Number			
Investigation #2 -- NDA Number			
Investigation #3 -- NDA Number			

If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Investigation #1	
Investigation #2	
Investigation #3	

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a. For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
IND#:				
Explain:				

Investigation #2	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
IND#:				
Explain:				

Investigation #3	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
IND#:				
Explain:				

b. For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
IND#:				
Explain:				

Investigation #2	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
IND#:				
Explain:				

Investigation #3	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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IND#:			
Explain:			
c. Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)		Yes	No
If yes, explain:			



Signature of PM/CSO *[Handwritten Signature]*
 Date: 8/30/2000

Signature of Division Director *Heidi Johnson MD*
 Date: 9/1/2000

cc:
 Original NDA
 Division File
 HFD-93 Mary Ann Holovac



CERTIFICATION: DEBARRED PERSONS

Bristol-Myers Squibb certifies that it has not used and will not use the services of any person listed as debarred as of the September 28, 1998 Debarment List under Section 306 (a) or (b) of the Federal Food and Drug Cosmetic Act [21 U.S.C. 355 (a) or (b)] in any capacity, in connection with this Application for VIDEX® (didanosine) Chewable/Dispersible Tablets.

Cynthia F. Piccirillo

Cynthia F. Piccirillo
Associate Director
Regulatory Science
Bristol-Myers Squibb Company
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492
(203) 677-7625

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MEMORANDUM OF TELEPHONE FACSIMILE CORRESPONDENCE

Date: June 30, 2000

To: Cynthia Piccirillo
Associate Director, Regulatory Affairs

Address: Bristol-Myers Squibb
Pharmaceutical Research Institute
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

From: Destry M. Sullivan, M.S., Regulatory Project Manager, HFD-530

Through: Russell Fleischer, PA-C, M.P.H., Medical Officer, HFD-530 *RF*
Therese Cvetkovich, M.D., Medical Team Leader, HFD-530 *TC*
Greg Soon, Ph.D., Statistical Team Leader (Acting), HFD-530 *GS* *6/30/00*

Subject: Labeling Supplement, VIDEX®, NDA 20-154/SE8-033

Reference is made to your submission of the final study report for BMS study AI454-148, dated March 21, 2000. Due to a recent modification of the definition for viral failure by DAVDP, the following analysis is requested for Study 148.

Please perform the following calculations using $LOQ = \text{---}$ and then $LOQ = \text{---}$

Please complete the request by 7/10/2000. To save time, you may send the results electronically first.

The new algorithm:

It is recommended that time to virologic failure be computed using the following algorithm:

- a. For the b and c below, discard all visits with no data. In what follows, visit means visit with an observed viral load. All available visits, including off-schedule visits and post Week 48 visits, should be used for the calculation.
- b. Subjects who never achieved confirmed $<LOQ$ (two consecutive visits $<LOQ$) before any of the following events will be considered to have failed at time 0.
 - i. Death
 - ii. HIV disease progression
 - iii. Discontinuation or switching of study medications. Temporary discontinuation or dose reduction of study medications may be ignored. Discontinuation or dose reduction of



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-156/S-025

MAY 2 2000

Bristol-Myers Squibb Company
5 Research Parkway
Wallingford, CT 06492

Attention: Cynthia F. Piccirillo, Associate Director Regulatory Science

Dear Ms. Piccirillo:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Videx® (didanosine)

NDA Number: 20-156

Supplement Number: S-025

Date of Supplement: March 21, 2000

Date of Receipt: March 21, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on May 20, 2000 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Anti-Viral Drug Products, HFD-530
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,


Anthony W. DeCicco

Supervisory Consumer Safety Officer
Division of Anti-Viral Drug Products, HFD-530
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

NDA 20-156/S-025
Page 2

cc:

Original NDA 20-156/S-025
HFD-530/Div. Files
HFD-530/CSO/D. Sullivan

SUPPLEMENT ACKNOWLEDGEMENT

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DEPARTMENT OF HEALTH & HUMAN SERVICES

HFD 530
SILIVAN
Public Health Service

NDA 20-154/S-033

Food and Drug Administration
Rockville MD 20857

MAY 2 2000

Bristol-Myers Squibb Company
5 Research Parkway
Wallingford, CT 06492

Attention: Cynthia F. Piccirillo, Associate Director Regulatory Science

Dear Ms. Piccirillo:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Videx® (didanosine)

NDA Number: 20-154

Supplement Number: S-033

Date of Supplement: March 21, 2000

Date of Receipt: March 21, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on May 20, 2000 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Anti-Viral Drug Products, HFD-530
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,



Anthony W. DeCicco
Supervisory Consumer Safety Officer
Division of Anti-Viral Drug Products, HFD-530
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

NDA 20-154/S-033

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cc:

Original NDA 20-154/S-033

HFD-530/Div. Files

HFD-530/CSO/D. Sullivan

SUPPLEMENT ACKNOWLEDGEMENT

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HFD 530 D. SULLIVAN



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 20-155/S-024

Food and Drug Administration
Rockville MD 20857

Bristol-Myers Squibb Company
5 Research Parkway
Wallingford, CT 06492

MAY 2 2000

Attention: Cynthia F Piccirillo, Associate Director Regulatory Science

Dear Ms. Piccirillo:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Videx® (didanosine)

NDA Number: 20-155

Supplement Number: S-024

Date of Supplement: March 21, 2000

Date of Receipt: March 21, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on May 20, 2000 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Anti-Viral Drug Products, HFD-530
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Anthony W. DeCicco
Supervisory Consumer Safety Officer
Division of Anti-Viral Drug Products, HFD-530
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

NDA 20-155/S-024
Page 2

cc:

Original NDA 20-155/S-024
HFD-530/Div. Files
HFD-530/CSO/D. Sullivan

SUPPLEMENT ACKNOWLEDGEMENT

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MEMORANDUM OF TELEPHONE FACSIMILE CORRESPONDENCE

Date: May 8, 2000

To: Cynthia Piccirillo
Associate Director, Regulatory Affairs

FILE COPY

Address: Bristol-Myers Squibb
Pharmaceutical Research Institute
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

From: Destry M. Sullivan, M.S., Regulatory Management Officer, HFD-530

Through: Russell Fleischer, PA-C, M.P.H., Medical Officer, HFD-530
Therese Cvetkovich, M.D., Medical Team Leader, HFD-530

Subject: Labeling Supplement, VIDEX®, NDA 20-154/SE8-033

Reference is made to your submission of the final study report for BMS study AI454-148, dated March 21, 2000:

1. Based on the lack of durability found in the treatment arm that contained once daily dosing of VIDEX®, please provide your justification for retaining the once daily dosing frequency recommendation in the VIDEX® label.

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.

Destry M. Sullivan, MS
Regulatory Management Officer
Division of Antiviral Drug Products

NDA 20-154
NDA 20-155
NDA 20-156

APR 25 2000

Bristol-Myers Squibb Company
Attention: Cynthia F. Piccirillo
Associate Director, Worldwide Regulatory Affairs
5 Research Parkway
Wallingford, CT 06492

Dear Ms. Piccirillo:

We have received your supplemental new drug applications (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Products:

VIDEX® (didanosine) Chewable/Dispersible Tablets (NDA 20-154), Buffered Powder for Oral Solution (NDA 20-155), and Pediatric Powder for Oral Solution (NDA 20-156).

Date of Applications:

March 21, 2000

Date of Receipt:

March 21, 2000

Our Reference Numbers:

NDA 20-154, 20-155, 20-156

We have not received the appropriate user fee for these applications. An application is considered incomplete and can not be accepted for filing until all fees owed have been paid. Therefore, these applications are not accepted for filing. We will not begin a review of these applications' adequacy for filing until FDA has been notified that the appropriate fees has been paid. Payment should be submitted to the following address:

Food and Drug Administration
P.O. Box 360909
Pittsburgh, PA 15251-6909

Checks sent by courier should be delivered to:

Mellon Bank
Three Mellon Bank Center
27th Floor (FDA 360909)
Pittsburgh, PA 15259-0001

NOTE: This address is for courier delivery only. Make sure the FDA Post Office Box Number (P.O. Box 360909) and user fee identification number is on the enclosed check.

The receipt date for these submissions (which begins the review for fileability) will be the date the review division is notified that payment was received by the bank.

Please cite the NDA numbers listed above at the top of the first page of any communications concerning these applications. All communications concerning these NDAs should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Antiviral Drug Products, HFD-530
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Antiviral Drug Products, HFD-530
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, call Destry Sullivan, MS, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. DeCicco', followed by the word 'FOR' in capital letters.

Anthony W. DeCicco, R.Ph.
Chief, Project Management Staff
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research



MEMORANDUM OF TELEPHONE FACSIMILE CORRESPONDENCE

Date: April 5, 2000

To: Cynthia Piccirillo
Associate Director, Regulatory Affairs

Address: Bristol-Myers Squibb
Pharmaceutical Research Institute
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

From: Destry M. Sullivan, M.S., Regulatory Management Officer, HFD-530

Through: Russell Fleischer, PA-C, M.P.H., Medical Officer, HFD-530 *RF by TC 4/7/00*
Therese Cvetkovich, M.D., Medical Team Leader, HFD-530 *TC 4/7/00*

Subject: Labeling Supplement, VIDEX®, NDA 20-154/SE8-033

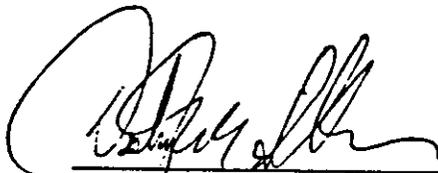
Reference is made to your submission of the final study report for BMS study AI454-148, dated March 21, 2000:

In study 148 similar antiviral activity between the two regimens was demonstrated at 24 weeks. However, at week 48 it appears that inferior antiviral efficacy is associated with the once daily ddi/d4T treatment arm, as demonstrated by analysis of both the < 400 c/mL and the < 50 c/mL results. These data raise serious questions about the durability of antiviral activity of ddi when dosed once daily, and the ability of 24 week activity results to predict durability at 48 weeks. Based on these results, we do not feel confident that the 24 week results from studies 152 and 158 (submitted for approval of the EC formulation of ddi) will be sufficient to allow us to make the appropriate conclusions upon which to take an action on the ddi EC NDA.

Given the need for 48 week durability data from studies 152 and 158, we request that you provide a proposal that would address our concerns as outlined above. We would be interested to discuss such a proposal with you. We would additionally be interested in any data to support BID dosing of ddi EC that you may have available.

Page: 2
April 7, 2000

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.**
Please feel free to contact me if you have any questions regarding the contents of this transmission.



Destry M. Sullivan, MS
Regulatory Management Officer
Division of Antiviral Drug Products

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MEMORANDUM OF TELEPHONE FACSIMILE CORRESPONDENCE

Date: April 3, 2000

To: Cynthia Piccirillo
Associate Director, Regulatory Affairs

Address: Bristol-Myers Squibb
Pharmaceutical Research Institute
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

From: Destry M. Sullivan, M.S., Regulatory Management Officer, HFD-530

Through: Russell Fleischer, PA-C, M.P.H., Medical Officer, HFD-530 *Rf 4/4/00*
Therese Cvetkovich, M.D., Medical Team Leader, HFD-530 *TC 4/4/00*

Subject: Labeling Supplement, VIDEX®, NDA 20-154/SE8-033

Reference is made to your submission of the final study report for BMS study AI454-148, dated March 21, 2000:

1. We note that included in the revised VIDEX® label, submitted with the final study report for study 148, you propose to state that the results of this study indicated that the two regimens produced similar antiviral activity. This description does not adequately convey the results of this study. Therefore, please prepare and submit a more detailed proposal for describing the results of this study. We expect this response to be received within 14 working days of this request.

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.


Destry M. Sullivan, MS
Regulatory Management Officer
Division of Antiviral Drug Products

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020155_5023 \$5024

020156_5024 \$5025

24/25

7/24/00