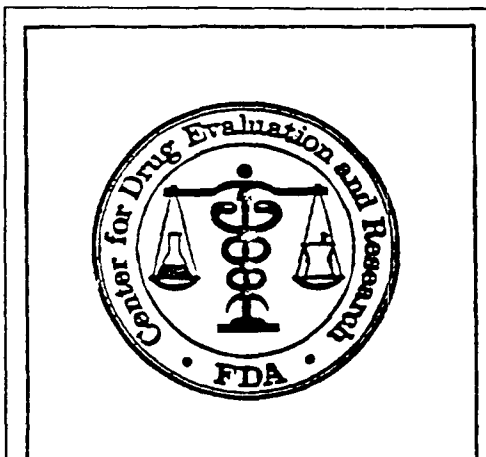


FACSIMILE TRANSMISSION
RECORD



From: Allan Fenselau, Ph.D.

Division of Reproductive and
Urologic Drug Products, HFD-580

Phone 301-827-4260

Fax 301-827-4267

Date: May 5, 2003

To: Name Magaret Foley
Company Bayer Corporation
City _____ State _____

Phone # 203-812-2147

FAX # 203-812-5029

Number of Pages (INCLUDING COVER PAGE) 2

Please telephone (301) 827-4260 IMMEDIATELY if re-transmission is necessary.

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Ms. Foley:

NDA 21-400

Please respond to the following request for information by 15-MAY-03. Please let me know if this deadline cannot be met. If you have any questions about specific items in the list or any other points in need of clarification, just call me or the project manager Eufrecina DeGuia (301-827-4260).

Allan Fenselau, Ph.D.
Review Chemist

These comments are being provided to you prior to completion of our review of the application to give you preliminary notice of issues that have been identified. Per the user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and are subject to change as the review of your application is finalized. In addition, we may identify other information that must be provided prior to approval of this application. If you choose to respond to the issues raised in this letter during this review cycle, depending on the timing of your response, as per the user fee reauthorization agreements, we may or may not be able to consider your response prior to taking an action on your application during this review cycle.

NOTE: Please provide the appropriate information as an amendment to the submission.

INFORMATION REQUEST

Chemist's Concerns

1. Provide an update of results from all stability studies involving the commercial-sized batches—Batch Nos. 845562K (5mg tablet strength), 845551A (10mg tablet strength), and 845549T (20mg tablet strength). Include data from both accelerated (40°C/75% relative humidity [RH]) and normal (25°C/60% RH) storage conditions.

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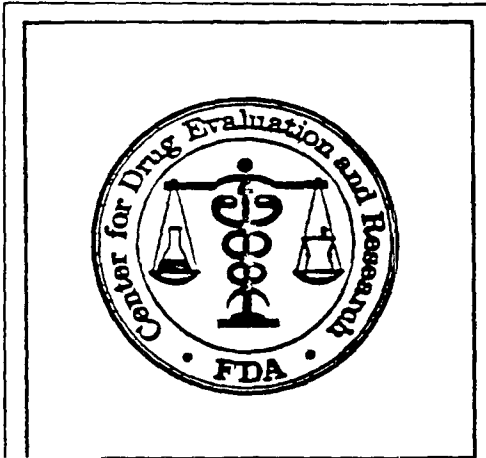
This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.

/s/

Allan Fenselau
5/5/03 09:47:15 AM
CHEMIST

David T. Lin
5/5/03 09:51:34 AM
CHEMIST
I concur.

FACSIMILE TRANSMISSION
RECORD



From: Allan Fenselau, Ph.D.

Division of Reproductive and
Urologic Drug Products, HFD-580

Phone 301-827-4260

Fax 301-827-4267

Date: April 8, 2003

To: Name Mary E. Taylor, M.P.H.
Company Bayer Corporation
City _____ State _____

Phone # 203-812-2678

FAX # 203-812-5364

Number of Pages (INCLUDING COVER PAGE) 2

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Ms. Taylor:

NDA 21-400

Please respond to the following request for information by 23-APR-03. Please let me know if this deadline cannot be met. If you have any questions about specific items in the list or any other points in need of clarification, just call me or the project manager Eufrecina DeGuia (301-827-4260).

Allan Fenselau, Ph.D.

Review Chemist

These comments are being provided to you prior to completion of our review of the application to give you preliminary notice of issues that have been identified. Per the user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and are subject to change as the review of your application is finalized. In addition, we may identify other information that must be provided prior to approval of this application. If you choose to respond to the issues raised in this letter during this review cycle, depending on the timing of your response, as per the user fee reauthorization agreements, we may or may not be able to consider your response prior to taking an action on your application during this review cycle.

NOTE: Please provide the appropriate information as an amendment to the submission.

INFORMATION REQUEST

Chemist's Concerns

1. Consider the use of one attribute for describing the physical appearance of the Levitra tablets. The release specification lists three attributes (Formulation, Format, and Colour) and the regulatory ("shelf life") specification lists only Appearance.
2. Confirm that, in accord with Test Procedure T.02.02-10, _____ will be the regulatory test method in the drug product specification for both Assay and Content Uniformity. Revise the "shelf life" specification shown in Table 4-2 in the "CMC Summary" that lists _____ under "Test Methods" for Assay and Content Uniformity.
3. Confirm that the method validation package has been updated to include tests for the 2.5mg tablet as well as the 5mg, 10mg, and 20mg tablets.
4. Confirm that the lot expiry date is based on the date of tablet manufacture and not on the packaging date.
5. Confirm that, in accord with your agreement regarding the 5mg, 10mg, and 20mg tablets (see the 08-JUL-2002 amendment), you will re-evaluate the acceptance criteria for the degradant content of the 2.5mg tablets one year after NDA approval.
6. Provide specific information for the carrying out the following: "The number of batches tested will be statistically based on the number of batches released that year." [See p. 2 of T.04.21-02: Follow Up Stability Data.] Unclear is the meaning of "statistically based."
7. Confirm that extension of shelf life will be based on data from the first three commercial batches and that microbiological testing will be performed at the time station proposed to represent the end of shelf life.

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this page is the manifestation of the electronic signature.

/s/

Allan Fenselau
4/8/03 12:31:58 PM
CHEMIST

David T. Lin
4/8/03 12:38:22 PM
CHEMIST
I concur.

NDA 21-400

Levitra® (vardenafil hydrochloride) Tablets

Bayer Healthcare

Advisory Committee

The QT data for this application was presented at a Cardio-Renal Advisory
Committee on May 29, 2003.

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No Federal Register Notices were published regarding this application.

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
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Degua, Eufrecina P

From: Houn, Florence
Sent: Friday, July 19, 2002 9:07 AM
To: Degua, Eufrecina P
Subject: FW: Vardenafil

Please include this email in the official Vardenafil package. Thanks. Flo

-----Original Message-----

From: Stockbridge, Norman L
Sent: Wednesday, July 17, 2002 12:59 PM
To: Shames, Daniel A; Benson, George; Houn, Florence; Hirsch, Mark S
Cc: Throckmorton, Douglas C
Subject: Vardenafil

Doug and I have taken a very minutes to discuss this proposal. Here are some pertinent considerations:
(1) 20 mg is closer to a max tolerated dose. Higher doses gave lots of back pain. Only the label would discourage use up to at least 20 mg, and that doesn't seem to be much of a deterrent.
(2) Vardenafil is a 3A4 substrate and the antiviral drugs have big (>10x) effects that would push plasma levels from even a 2.5 mg dose up near the mean for a 40 mg dose. Again, you have to depend on the label to prevent that.
(3) Study 94 results are suggestive that doses 10-80 mg have similar effects on QT.
(4) I don't believe you can rule out even a 10-ms effect at 40 mg. None of these data have the active-control assay validation we are seeking.
In summary, neither of us think the proposal is encouraging.

The drug name mix-up was my fault.

--Norman

-----Original Message-----

From: Throckmorton, Douglas C
Sent: Wednesday, July 17, 2002 12:34 PM
To: Stockbridge, Norman L
Subject: FW: _____

Norinan, see below. The sponsor is proposing to market _____ of drug, and wonders if that alters your level of comfort. I don't know the answer, but seems unlikely. Please let me know. DCT

-----Original Message-----

From: Shames, Daniel A
Sent: Wednesday, July 17, 2002 11:41 AM
To: Throckmorton, Douglas C
Cc: Houn, Florence
Subject: RE: _____

Doug,
The drug is Vardenafil (Bayer). Also please read the email from 10:41 of today (7/17) which I meant to send to you.
Dan

-----Original Message-----

From: Houn, Florence
Sent: Wednesday, July 17, 2002 10:47 AM
To: Shames, Daniel A; Hirsch, Mark S; Benson, George
Cc: Stockbridge, Norman L
Subject: RE: _____

The drug is not _____ but vardenafil.

Dan, your email, although addressing "Doug", is really to the team, plus Norm. The team needs to assess if there is enough QT info for 2.5, 5, 10 or just 2.5 and 5 or just 2.5. (It would be okay to approve a single dose that is S and E.)

Flo

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MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION
 CENTER FOR DRUG EVALUATION AND RESEARCH

Date: October 18, 2001

From: Jeanine Best, M.S.N., R.N.
 Senior Regulatory Associate
 Division of Reproductive and Urologic Drug Products (HFD-580)

Subject: Review of Financial Disclosure Documents

To: NDA 21-400

I have reviewed the financial disclosure information submitted by Bayer Corporation in support of their NDA 21-400.

Nine studies were conducted to assess the safety and efficacy of Nuviva™ (vardenafil HCL) Tablets 5 mg, 10 mg, 20 mg. This product is proposed for the treatment of erectile dysfunction. The study numbers and the results of the review of financial disclosure documents are summarized below:

Study Number/Title	Study Status	Financial Disclosure Review
Study 100249 / "Randomized, Double-Blind, Placebo-Controlled, Multicenter, Fixed-Dose, Parallel Group, 6-Month Comparison Study to Investigate the Efficacy and Safety of the Phosphodiesterase Type V Inhibitor BAY 38-9456 in Males With Erectile Dysfunction"	Study Start: March 29, 2000 Study Complete: March 2, 2001	Appropriate documentation received, financial disclosure submitted.
Study 10128 / "A Randomized, Double-Blind, Placebo- and Active (Viagra®)- Controlled, Multi-Center, Fixed-Dose, Parallel Group Study to Investigate the Efficacy and Safety of the Phosphodiesterase Type 5 Inhibitor BAY 38-9456 in Men With Erectile Dysfunction"	Study Start: May 24, 2000 Study Complete: January 12, 2001	Appropriate documentation received, no financial disclosure submitted.
Study 100250 / "A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Fixed-Dose, Parallel Group, 3-Month Comparison Study to Investigate the Efficacy and Safety of the Phosphodiesterase Type V Inhibitor BAY 38-9456 in Males with Erectile Dysfunction and Diabetes Mellitus"	Study Start: April 7, 2000 Study Complete: November 7, 2000	Appropriate documentation received, no financial disclosure submitted.

Study 100285 / "A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Fixed-Dose, Parallel Group, 3-Month Comparison Study to Investigate the Efficacy and Safety of the Phosphodiesterase Type V Inhibitor BAY 38-9456 in Males with Erectile Dysfunction Following Radical Prostatectomy"	Study Start: July 11, 2000 Study Complete: June 1, 2001	Appropriate documentation received, no financial disclosure submitted.
Study 10125 / "A Randomized, Double-Blind, Multi-Center, Fixed-Dose, Parallel Group, Twelve Month Study to Investigate the Safety and Tolerability the Phosphodiesterase Type 5 Inhibitor BAY 38-9456 in the Treatment of Patients with Erectile Dysfunction"	Study Start: April 7, 2000 Study Complete: February 26, 2001	Appropriate documentation received, no financial disclosure submitted.
Study 100312/ "Active Drug extension to Study 100250 (A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Fixed-Dose, Parallel Group, 3-Month Comparison Study to Investigate the Efficacy and Safety of the Phosphodiesterase Type V Inhibitor BAY 38-9456 in Males with Erectile Dysfunction and Diabetes Mellitus)"	Study Start: August 9, 2000 Study Complete: March 9, 2001	Appropriate documentation received, no financial disclosure submitted.
Study 10152/ "An Open-Label, Single-Group, Multi-Center, Fixed-Dose, Six-Month Study to Investigate the Safety and Tolerability of the Phosphodiesterase Type 5 Inhibitor BAY 38-9456 in the Treatment of Patients with Erectile Dysfunction"	Study Start: June 14, 2000 Study Complete: March 28, 2001	Appropriate documentation received, no financial disclosure submitted.
Study 10232/ "A Phase III, Randomized, Double Dummy, Placebo-Controlled, Multi-Center, Fixed-Dose, Parallel-Group Study Appropriate documentation received, no financial disclosure submitted.	Study Start: October 9, 2000 Study Complete: April 18, 2001	Appropriate documentation received, no financial disclosure submitted.
Study 100199/ "A Phase IIb Randomized, Placebo-Controlled, Multi-Center, Parallel-Group Study to Investigate the Efficacy and Safety of Three Doses of Bayer 38-9456 Versus Placebo in the Treatment of Patients With Erectile Dysfunction".	Study Start: May 31, 1999 Study Complete: December 20, 1999	Appropriate documentation received, no financial disclosure submitted.

Documents Reviewed:

- FDA Form 3454, Certification: Financial Interests and Arrangements of Clinical Investigators
- Financial Disclosure Information Tables submitted by the sponsor
- Clinical Study Reports

Study 100249

There were 217 principal and subinvestigators (investigators) at 60 sites in this trial (850 patients). One site had a subinvestigator for whom financial disclosure information was not received:

- Site 7 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 0.1% of the patients in the study. The sponsor reported that this subinvestigator did not enroll any patients in the study.

One site had a subinvestigator with disclosable information:

- Site 23 (U.S.); _____ reported _____ in the sponsor of the covered study; _____ this site enrolled 2.1% of the patients in the study.

Of the remaining investigators, none had any disclosable information.

Study 10128

There were 48 principal and subinvestigators (investigators) at 47 sites in this trial (871 patients). Financial disclosure information was received from all investigators; none had any disclosable information.

Study 100250

There were 130 principal and subinvestigators (investigators) at 47 sites in this trial (452 patients). Three sites had subinvestigators for whom financial disclosure information was not received:

- Site 12 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 2.2% of the patients in the study
- Site 14 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 8.6% of the patients in the study
- Site 30 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 0.9% of the patients in the study

The sponsor reported that none of these subinvestigators enrolled any patients in the study. Of the remaining investigators, none had any disclosable information.

Study 100285

There were 212 principal and subinvestigators (investigators) at 65 sites in this trial (440 patients). One site had an investigator for whom financial disclosure information was not received:

- Site 12 (Canada) had 1 investigator who did not supply financial disclosure data; this site enrolled 0.7% of the patients in the study; the sponsor reported that the investigator died and that financial disclosure information is not available.

Two sites had subinvestigators who did not supply financial disclosure information:

- Site 110 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 2.0% of the patients in the study
- Site 118 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 3.4% of the patients in the study

The sponsor reported that neither of these subinvestigators enrolled any patients in the study. Of the remaining investigators, none had any disclosable information.

Study 10125

There were 155 principal and subinvestigators (investigators) at 72 sites in this trial (1357 patients). One site had 4 subinvestigators for whom financial disclosure information was not received:

- Site 904 (Canada) had 4 subinvestigators who did not supply financial disclosure information; this site enrolled 0.7% of the patients in the study; the sponsor reported that none of these subinvestigators enrolled any patients in the study.

Of the remaining investigators, none had any disclosable information.

Study 100312

There were 124 principal and subinvestigators (investigators) at 45 sites in this trial (340 patients). Three sites had subinvestigators for whom financial disclosure information was not received:

- Site 12 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 2.9% of the patients in the study
- Site 14 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 11.5% of the patients in the study
- Site 30 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 1.2% of the patients in the study

The sponsor reported that none of these subinvestigators enrolled any patients in the study. Of the remaining investigators, none had any disclosable information.

Study 10152

There were 78 principal and subinvestigators (investigators) at 57 sites in this trial (327 patients). There were 23 investigators at 12 sites for whom financial disclosure information was not received. None of these sites enrolled patients who were included in the interim analysis report submitted in the NDA. Updated financial disclosure will be submitted to the NDA with the final study report:

- Site 16 (Netherlands), 1 principal investigator
- Site 18 (Netherlands), 1 principal investigator; 1 subinvestigator
- Site 19 (Poland), 1 principal investigator; 2 subinvestigators
- Site 20 (Poland), 1 principal investigator; 2 subinvestigators
- Site 44 (Hungary), 1 principal investigator
- Site 49 (Portugal), 1 principal investigator; 3 subinvestigators
- Site 50 (Portugal), 1 principal investigator; 2 subinvestigators
- Site 51 (Portugal), 1 principal investigator; 1 subinvestigator
- Site 1 (South Africa), 1 principal investigator
- Site 2 (South Africa), 1 principal investigator
- Site 3 (South Africa), 1 principal investigator
- Site 4 South Africa), 1 principal investigator

Of the remaining investigators, none had any disclosable information.

Study 10232

There were 42 principal and subinvestigators (investigators) at 42 sites in this trial (663 patients). Financial disclosure information was received from all investigators; none had any disclosable information.

Study 100199

There were 121 principal and subinvestigators (investigators) at 39 sites in this trial (749 patients). One site had 1 subinvestigator for whom financial disclosure information was not received:

- Site 0109 (U.S.) had 1 subinvestigator who did not supply financial disclosure information; this site enrolled 2.5% of the patients in the study; the sponsor reported that this subinvestigator did not enroll any patients in the study.

Of the remaining investigators, none had any disclosable information.

Conclusion:

Adequate documentation was submitted to comply with 21 CFR 54; the rate of return is acceptable. There was no disclosure of financial interests at this time that could bias the outcome of the trials; the one site with a subinvestigator with disclosable information only enrolled 2.1% of the patients in the study. Updated financial disclosure information for Study 10152 will be reviewed when submitted to the NDA with the final study report.

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/s/

Jeanine Best
10/18/01 09:41:21 AM
CSO

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

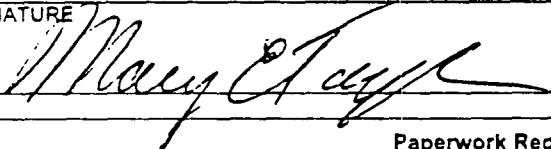
With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	See Attached	<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Mary Taylor	Director, Regulatory Affairs
FIRM/ORGANIZATION	
Bayer Corporation, Pharmaceutical Division	
SIGNATURE	DATE
	September 24, 2001

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Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

19.1 Financial Disclosure Information

19.1.1 Studies #100250 and 100312 (extension)

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
CANADA				
Gottesman-901	7	Irving S Gottesman, MD	Yes	No
Maheux-902	11	Pierre Maheux, MD	Yes	No
Murphy-903	10	Liam J Murphy, MD	Yes	No
Salgado deLeon-904	7	Luis Salgado deLeon, MD	Yes	No
Skamene-905	13	Alexander Skamene, MD	Yes	No
Yale-906	9	Jean-Francois Yale, MD	Yes	No
Bailey-907	5	Gordon R Bailey, MD	Yes	No
Bellavance-908	2	Gilles Bellavance, MD	Yes	No
St-Pierre-909	13	Bruno St-Pierre, MD	Yes	No
Ryan-910	9	Edmond A Ryan, MD	Yes	No
UNITED STATES				
Ahmann-1	1	Andrew Ahmann, MD	Yes	No
Brito-3	0	C. Gilberto Brito, MD	Yes	No
Brown-4	5	Ann Brown, MD	Yes	No
Carson-5	8	Cullev C Carson, MD	Yes	No
			Yes	No
			Yes	No
Haag-6	6	Burrill L Haag, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
Dula-7	15	Eugene Dula, MD	Yes	No
			Yes	No
Fischer-8	27	Jerome S Fischer, MD	Yes	No
			Yes	No
			Yes	No
Goldstein-9	12	Irwin Goldstein, MD	Yes	No
			Yes	No
Juneja-10	8	Rattan Juneja, MD	Yes	No
			Yes	No
			Yes	No
Jayson-11	10	Maury A Jayson, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Lewis-12	10	Ronald W Lewis, MD	Yes Yes Yes 'A)	No No No (A)
McMurray-13	6	James McMurray, MD	Yes Yes Yes	No No No
Mollen-14	39	Martin D Mollen, MD	Yes (A)	No (A)
Razzetti-15	5	Albert J Razzetti, MD	Yes Yes Yes Yes Yes	No No No No No
Rendell-16	14	Marc S Rendell, MD	Yes Yes	No No
Reusch-17	7	Jane Reusch, MD	Yes Yes	No No
Ritter-18	2	Henry Ritter, Jr., MD	Yes	No
Shabsigh-19	13	Ridwan Shabsigh, MD	Yes	No
Sharp-20	17	Stephan C Sharp, MD	Yes Yes	No No
Weinstein-21	22	Richard L Weinstein, MD	Yes	No
Weiss-22	3	Staurt Weiss, MD	Yes Yes Yes	No No No
Zinner-23	11	Norman Zinner, MD	Yes Yes Yes	No No No
Young-24	30	Jay M Young, MD	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No No No No No
Linden-25	11	Dennis H Linden, MD	Yes Yes Yes	No No No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Blasser-26	8	Marc Blasser, MD	Yes Yes Yes	No No No
Mobley-27	4	David F Moblev, MD	Yes es	No No
Chu-28	32	Franklin M Chu, MD	Yes Yes	No No
Modarelli-29	2	Robert O Modarelli, MD	Yes es	No No
Watson-30	4	Daniel L Watson, MD	Yes es Yes es (A) Yes	No No No No (A) No
Fishman-31	3	Irving J Fishman, MD	Yes	No
Antar-33	3	Mohamed Antar, MD	Yes es Yes es	No No No No
Meneghini-35	5	Luiqi Meneghini, MD	Yes es Yes Yes	No No No No
Hollander-37	2	Jay B Hollander, MD	Yes es	No No
Schneider-38	2	Stephen H Schneider, MD	Yes Yes Yes Yes	No No No No
Goldstone-39	0	Lawrence Goldstone, MD	Yes	No
Heuer-40	5	Marvin Heuer, MD	Yes es Yes Yes	No No No No
McFadden-43	5	Michael McFadden, MD	Yes	No
Fairchild-45	0	Thomas Fairchild, MD	Yes Yes Yes	No No No
Kilbane-46	4	Anthony J Kilbane, MD	Yes Yes Yes Yes	No No No No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Yeoman-47	5	Garv D Yeoman, MD	Yes Yes	No No
Brosman-48	0	Stanley Brosman, MD	Yes	No

APPEARS THIS WAY
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For explanations of (A), (B), and (C), please see last page of this document.

19.1.2 Study #100249

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
CANADA				
Casey-901	14	Richard Casey, MD	Yes	No
Barkin-902	16	Jack Barkin, MD	Yes	No
Valiquette-903	7	Luc Valiquette, MD	Yes	No
Patrick-904	7	Allan B Patrick, MD	Yes	No
Elhilali-905	13	Mostafa M Elhilali, MD	Yes	No
Pommerville-906	3	Peter J Pommerville, MD	Yes	No
Greenspan-907	6	Michael Greenspan, MD	Yes	No
Zadra-908	15	Joseph Zadra, MD	Yes	No
Matthews-909	9	Keith Matthews, MD	Yes	No
Abele-910	2	Randall P Abele, MD	Yes	No
Fields-911	6	Louis Fields, MD	Yes	No
UNITED STATES				
Childs-1	12	Stacy Childs, MD	Yes	No
Ellsworth-2	0	Pamela I Ellsworth, MD	Yes	No
Truitt-3	1	Timothy S Truitt, MD	Yes	No
Donatucci-4	23	Craig F Donatucci, MD	Yes	No
Price-5	37	V. Gary Price, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
Krane-6	0	Robert J Krane, MD	Yes	No
Raad-7	14	George Raad, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
Gilderman-8	19	Larry I Gilderman, DO	Yes	No
			Yes	No
Fitch-9	14	William P Fitch, III, MD	Yes	No
Tepas-10	11	Joseph J Tepas, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Talley-11	17	David Talley, MD	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No No No No
Auerbach-12	52	Stephen M Auerbach, MD	Yes Yes	No No
Bergner-13	28	Donald Bergner, MD	Yes es s	No No No
Cook-14	21	David O Cook, MD	Yes Yes Yes Yes Yes Yes	No No No No No No
Deeths-15	15	Jeffrey Deeths, MD	Yes Yes Yes Yes Yes Yes Yes	No No No No No No No
Fuselier-16	0	Harold A Fuselier, MD	Yes Yes Yes es	No No No No
Krieger-17	0	John N Krieger, MD	Yes Yes	No No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Leitner-18	12	William A Leitner, MD	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No No No No No
McVary-19	9	Kevin T McVary, MD	Yes Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No No
McCullough-20	4	Andrew McCullough, MD	Yes	No
Padma-Nathan-22	53	Harin Padma-Nathan, MD	Yes Yes	No No
Steidle-23	17	Christopher P Steidle, MD	Yes Yes Yes Yes Yes	No No Yes - No No
Storrie-24	32	Cecile Storrie, MD	Yes Yes Yes	No No No
Andriole-25	6	Gerald L Andriole, MD	Yes Yes Yes	No No No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Barzell-26	5	Winston Barzell, MD	Yes Yes Yes Yes	No No No No
Cohen-27	18	Selwyn Cohen, MD	Yes es	No No
Foote-28	4	Jenelle E Foote, MD	Yes Yes (A)	No No (A)
Goldfischer-29	20	Evan Goldfischer, MD	Yes Yes Yes Yes	No No No No
Sieber-30	8	Paul R Sieber, MD	Yes Yes Yes Yes Yes Yes	No No No No No No
Skolnick-31	7	Alan W Skolnick, MD	Yes Yes	No No
Vukasin-32	0	Alexander Vukasin, MD	Yes Yes Yes Yes	No No No No
Karlin-33	31	Gary S Karlin, MD	Yes s	No No
Hellstrom-34	3	Wayne J Hellstrom, MD	Yes Yes	No No
Lau-35	7	Alan Lau, MD	Yes Yes Yes Yes	No No No No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Monnig-36	9	William B Monnig, MD	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No No No
Govier-37	4	Fred Govier, MD	Yes Yes Yes	No No No
Frankel-38	5	Jeffrey Frankel, MD	Yes Yes	No No
Peterson-39	5	Jon Lee Peterson, MD	Yes Yes	No No
Gottesman-40	0	James E Gottesman, MD	Yes Yes	No No
Melman-42	2	Arnold Melman, MD	Yes Yes	No No
Gittelman-44	56	Marc Gittelman, MD	Yes Yes Yes Yes	No No No No
Feldman-45	18	Robert A Feldman, MD	Yes Yes Yes Yes Yes Yes	No No No No No No
Fincher-46	17	Roger Fincher, MD	Yes (A)	No (A)
Lubensky-48	6	Jack Lubensky, MD	Yes Yes Yes	No No No
Herring-51	20	Charles B Herrin, MD	Yes Yes Yes Yes Yes	No No No No No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.3 Study #100199

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
BELGIUM				
Duyck-0001	50	F Duyck	Yes	No
Merckx-0002	6	L Merckx	Yes	No
FRANCE				
Buvat-0026	45	J Buvat	Yes Yes Yes	No No No
Cuzin-0023	40	BACV Cuzin	Yes Yes	No No
Fourcade-0022	8	R Fourcade	Yes Yes	No No
Giuliano-0025	41	F Giuliano	Yes Yes	No No
Sarramon-0024	4	JP Sarramon	Yes Yes Yes Yes	No No No No
GERMANY				
Emrich-0015	13	HM Emrich	Yes Yes Yes Yes	No No No No
Porst-0016	55	H Porst	Yes	No
Grohmann-0017	15	W Grohmann	Yes	No
Lenk-0018	1	VS Lenk	Yes	No
Nietzsch-0019	21	DH Nietzsch	Yes	No No
Szymula-0020	22	S Szymula	Yes Yes	No No
Vilmar-0021	22	W Vilmar	Yes	No
NETHERLANDS				
Asscheman-0012	24	H Asscheman	Yes Yes	No No
Kropman-0013	13	RF Kropman	Yes Yes	No No
Lycklama-0014	8	AAB Lycklama	Yes Yes	No No
POLAND				
Borkowski-0009	16	A Borkowski	Yes Yes Yes Yes	No No No No
Krajka-0010	36	K Krajka	Yes Yes	No No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.3 Study #100199

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
			Yes Yes	No No
SOUTH AFRICA				
Mackenzie-0004	12	TM Mackenzie	Yes Yes	No No
Robertson-0003	15	LI Robertson	Yes	No
Schmidt-0005	16	AC Schmidt	Yes	No
Sleep-0006	4	DJ Sleep	Yes Yes Yes	No No No
Wing-0007	33	JR Wing	Yes Yes Yes	No No No
UNITED STATES				
Feldman-0101	23	RA Feldman	Yes Yes Yes Yes Yes Yes	No No No No No No
Auerbach-0116	12	SM Auerbach	Yes Yes Yes Yes	No No No No
Steidle-0112	33	CP Steidle	Yes Yes Yes Yes Yes	No No No No No
Klimberg-0107	17	IW Klimberg	Yes Yes	No No
Padma-Nathan-0108	31	H Padma-Nathan	Yes Yes Yes	No No No
Gleason-0103	13	DM Gleason	Yes Yes Yes Yes Yes Yes	No No No No No No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.3 Study #100199

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Kaufman-0106	3	JM Kaufman	Yes Yes	No No
Young-0115	16	JM Young	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No No No No No
Storrie-0113	8	MC Storrie	Yes Yes Yes Yes Yes	No No No No No
Garland-0102	9	WT Garland	Yes	No
White-0114	1	CF White	Yes Yes Yes	No No No
Rosen-0109	19	RC Rosen	Yes (A)	No (A)
Harris-0105	9	RG Harris	Yes Yes Yes	No No No
Sharp-0110	6	SC Sharp	Yes Yes Yes	No No No
Smith-0111	29	WB Smith	Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.4 Study #100285

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
CANADA				
Barkin-1	9	Jack Barkin, MD	Yes	No
Brock-2	18	Gerald Brock, MD	Yes	No
Carrier-3	1	Serge Carrier, MD	Yes	No
Casey-4	19	Richard Casey, MD	Yes	No
Collins-5	0	John Collins, MD	Yes	No
Donnelly-6	9	Bryan Donnelly, MD	Yes	No
Grantmyre-7	6	John Grantmyre, MD	Yes	No
Greenspan-8	6	Michael Greenspan, MD	Yes	No
Abele-10	4	Randall P Abele, MD	Yes	No
Patrick-11	3	Allan B Patrick, MD	Yes	No
Ramsey-12	3	E. W. Ramsey, MD	(C)	(C)
Simard-13	5	Jean Simard, MD	Yes	No
Valiquette-14	7	Luc Valiquette, MD	Yes	No
Zadra-15	7	Joseph Zadra, MD	Yes	No
Kuzmarov-16	1	Irwin Kuzmarov, MD	Yes	No
Vezina-17	4	Jean-guy Vezina, MD	Yes	No
Carmel-18	7	Michel Carmel, MD	Yes	No
Jarvi-19	12	Keith Jarvi, MD	Yes	No
Lau-20	2	Peter Lau, MD	Yes	No
Morse-21	9	Michael J Morse, MD	Yes	No
Pommerville-22	18	Peter J Pommerville, MD	Yes	No
Herschorn-23	6	Sender Herschorn, MD	Yes	No
Love-24	10	William Love, MD	Yes	No
Gleave-25	10	Martin Gleave, MD	Yes	No
UNITED STATES				
Goldstone-101	0	Lawrence Goldstone, MD	Yes	No
Bergreen-102	10	Peter W Bergreen, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
Padma-Nathan-103	33	Harin Padma-Nathan, MD	Yes	No
			Yes	No
			Yes	No
Burnett-104	4	Arthur L Burnett, MD	Yes	No
Carson-105	6	Culley C Carson, MD	Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.4 Study #100285

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
			Yes	No
			Yes	No
			Yes	No
Ellsworth-106	2	Pamela I Ellsworth, MD	Yes	No
Lipshultz-107	14	Larry I Lipshultz, MD	Yes	No
			Yes	No
Seftel-108	1	Allen D Seftel, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No
Shabsigh-109	8	Ridwan Shabsigh, MD	Yes	No
Wurzel-110	9	Rafael Wurzel, MD	Yes	No
			Yes	No
			Yes	(A)
Mulhall-111	0	John P Mulhall, MD	Yes	No
Jablonski-112	5	Donald Jablonski, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
Watson-113	3	Daniel L Watson, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
Cochran-114	11	James S Cochran, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
Karlin-115	16	Gary S Karlin, MD	Yes	No
			Yes	No
Langenstroer-116	8	Peter Langenstroer, MD	Yes	No
			Yes	No
			Yes	No
			Yes	No
Lewis-117	2	Ronald W Lewis, MD	Yes	No
			Yes	No
			Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.4 Study #100285

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
			Yes	No
Weiss-118	15	Robert E Weiss, MD	Yes (A)	No (A)
Schervish-119	8	Edward W Schervish, MD	Yes es es Yes Yes Yes	No No No No No No
Murdock-120	2	Myron I Murdock, MD	Yes Yes Yes	No No No
Sliwinski-121	21	Anthony Sliwinski, MD	Yes Yes	No No
Soloway-122		Mark Soloway, MD	Yes es	No No
Williams-123	5	Richard D Williams, MD	Yes Yes	No No
Nehra-124	5	Ajay Nehra, MD Robert Myers, MD	Yes es es Yes	No No No No
Vukasin-125	0	Alexander Vukasin, MD	Yes Yes Yes Yes es	No No No No No
Kaminetsky-126	2	Jed Kaminetsky, MD	Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.4 Study #100285

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Kleer-127	10	Eduardo Kleer, MD	Yes Yes Yes	No No No
Silbar-128	3	Elliott Silbar, MD	Yes Yes Yes	No No No
Hellstrom-129	5	Wayne J Hellstrom, MD	Yes Yes Yes	No No No
Stein-130	0	Bruce Stein, MD	Yes	No
Rajfer-131	6	Jacob Rajfer, MD	Yes s	No No
Sieber-133	4	Paul R Sieber, MD	Yes Yes Yes Yes es	No No No No No
Young-134	6	Jay M Young, MD	Yes Yes Yes Yes Yes Yes Yes Yes es Yes	No No No No No No No No No No
Kaufman-135	17	Joel M Kaufman, MD	Yes Yes Yes	No No No
Goldfischer-136	2	Evan Goldfischer, MD	Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Deeths-137	14	Jeoffrey Deeths, MD	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No No No No No No No No
Aliotta-138	0	Philip Aliotta, MD	Yes	No
Talley-139	3	David Talley, MD	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No No No No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Jayson-140	2	Maury A Jayson, MD 	Yes Yes Yes Yes	No No No No
Klimberg-141	1	Ira W Klimberg, MD 	Yes Yes	No No
Monnig-142	1	William Monnig, MD 	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No No No No No No No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.5 Study #10152

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
FRANCE				
Giuliano-1	0	Dr. Francois Giuliano	Yes Yes	No No
Buvat-2	27	Dr. Jacques Buvat	Yes Yes	No No
Sarramon-3	8	Pr. Jean-Pierre Sarramon	Yes	No
Cuzin-4	14	Dr. Beatrice Cuzin	Yes	No
Fourcade-5	7	Dr. Richard Fourcade	Yes	No
Chevallier-6		Dr. Daniel Chevallier	Yes	No
Schouman-7	4	Dr. Michel Schouman	Yes	No
Robert-8	2	Dr. Francois Robert	Yes	No
Faix-9	11	Dr. Antoine Faix	Yes	No
Marre-10	7	Dr. Michel Marre	Yes	No
NETHERLANDS				
Asscheman-16		Dr. Henk Asscheman	(B)	(B)
Kropman-18		Dr. Rene Franciscus Kropman	(B) (B)	(B) (B)
POLAND				
Krajka-19		Pr. Kazimierz Krajka	(B) (B) (B)	(B) (B) (B)
Borkowski-20		Pr. Andrzej Borkowski	(B) (B) (B)	(B) (B) (B)
BELGIUM				
Duyck-21	13	Dr. Francis Duyck	Yes Yes	No No
Merckx-22	0	Dr. Luc Merckx	Yes	No
Van Gaal-23	8	Pr. Luc Van Gaal	Yes Yes	No No
GERMANY				
Porst-24	35	Pr. Hartmut Porst	Yes	No
Hartmann-25	0	Pr. Uwe Hartmann	Yes Yes	No No
Grohmann-26	5	Dr. Walther Grohmann	Yes	No
Nietzsch-27	0	Dr. Detlef Nietzsch	Yes Yes	No No
Szymula-28	0	Dr. Silvio Szymula	Yes Yes	No No
Vilmar-29	3	Dr. Wolfgang Vilmar	Yes	No
Te Breuil-30	0	Dr. Wolfgang Te Breuil	Yes	No
Zumbe-31	0	PD Dr. Jurgen Zumbe	Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.5 Study #10152

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Schmidt-32	16	Dr. Rainer Schmidt	Yes	No
Knispel-33	5	Dr. H. H. Knispel	Yes	No
Genthner-34	15	Dr. Peter Genthner	Yes	No
Potempa-35	0	Dr. Dirk Potempa	Yes	No
Gratzke-36	0	Dr. Peter Gratzke	Yes	No
Vielsmeier-37	1	Dr. Georg Vielsmeier	Yes	No
Heim-38	5	Dr. Deszo Heim	Yes	No
Burgmayer-39	2	Dr. Franz Burgmayer	Yes	No
Bruns-40	4	Dr. Christoph Bruns	Yes	No
Samer-41	0	Dr. Holger Samer	Yes	No
Gohlke-42	2	Dr. Vera-Maria Gohlke	Yes	No
HUNGARY				
Toth-44		Prof. Csaba Toth	(B)	(B)
PORTUGAL				
Pimenta-49		Dr. Adriano Fernandes Pimenta	(B)	(B)
			(B)	(B)
			(B)	(B)
			(B)	(B)
Dias-50		Dr. Joao Real Dias	(B)	(B)
			(B)	(B)
			(B)	(B)
Monteiro-51		Dr. Leonidio Dias Monteiro	(B)	(B)
			(B)	(B)
SOUTH AFRICA				
Haffejee-1		Dr. Mohammed Haffejee	(B)	(B)
Schmidt-2		Dr. Abrie Schmidt	(B)	(B)
Robertson-3		Dr. Li Robertson	(B)	(B)
Mackenzie-4		Dr. T.M. Mackenzie	(B)	(B)
UNITED STATES				
Auerbach-1	4	Dr. Stephen Auerbach	Yes	No
Feldman-2	13	Dr. Robert Feldman	Yes	No
Garland-3	9	Dr. Thomas Garland	Yes	No
Gleason-4	1	Dr. Donald Gleason	Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Harris-5	34	Dr. Richard Harris	Yes	No
Klimberg-6	12	Dr. Ira Klimberg	Yes	No
Padma-Nathan-7	17	Dr. Harin Padma-Nathan	Yes	No
Rosen-8	11	Dr. Raymond Rosen	Yes	No
Smith-9	9	Dr. William Smith	Yes	No
Steidle-10	10	Dr. Christopher Steidle	Yes	No
Storrie-11	0	Dr. Cecile Storrie	Yes	No
White-12	13	Dr. Charles F White	Yes	No
Young-13	0	Dr. Jay M Young	Yes	No

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For explanations of (A), (B), and (C), please see last page of this document.

19.1.6 Study #10125 and 10573 (extension)

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
ARGENTINA				
Mazza-35	18	Mr. Dr. Osvaldo Mazza, MD	Yes Yes Yes Yes	No No No No
Gueglio-36	9	Mr. Dr. Guillermo Gueglio	Yes Yes Yes Yes Yes	No No No No No
Rivero-37	15	Mr. Dr. Miguel Rivero	Yes Yes	No No
Becher-38	17	Mr. Dr. Edgardo Becher	Yes Yes	No No
Bechara-39	30	Mr. Dr. Amado Bechara	Yes Yes Yes Yes	No No No No
Vazquez-40	7	Mr. Dr. José Vazquez	Yes Yes Yes	No No No
AUSTRALIA				
McMahon-45	20	Dr. Chris McMahon	Yes Yes Yes	No No No
Stuckey-46	21	Dr. Bronwyn Stuckey	Yes Yes Yes	No No No
Lording-47	17	Assoc Prof Douglas Lording	Yes Yes	No No
BRAZIL				
Teloken-22	14	Mr. Prof. Dr. Claudio Teloken	Yes Yes Yes Yes Yes	No No No No No
Claro-23	12	Mr. Dr. Joaquim Claro	Yes Yes	No No
Bertero-24	8	Mr. Dr. Eduardo Bertero	Yes	No
Glina-26	17	Mr. Dr. Sidney Glina	Yes Yes	No No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.6 Study #10125 and 10573 (extension)

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
			Yes	No
Faria-27	18	Mr. Dr. Geraldo Eduardo Faria	Yes	No
Jardim-28	6	Mr. Prof. Dr. Carlos Roberto Jardim	Yes	No
Martucci-29	6	Mr. Prof. Dr. Rubens Carlos Martucci	Yes Yes Yes Yes es	No No No No No
Chaves-30	6	Mr. Prof. Dr. Otto	Yes	No
CANADA				
Grantmyre-901	2	Dr. John Grantmyre	Yes es es	No No No
Brock-902	15	Dr. Gerald Brock	Yes Yes	No No
Carrier-903	16	Dr. Serge Carrier	Yes Yes	No No
Barr-904	9	Dr. Richard Barr	Yes Yes es Yes Yes (A) Yes (A) (A) (A) (A)	No No No No No (A) No (A) (A) (A) (A)
Morales-905	2	Dr. Alvaro Morales	Yes Yes	No No
Guertin-906	5	Dr. Benoit Guertin	Yes Yes Yes Yes Yes Yes	No No No No No No
CHILE				
Salazar-32	17	Mr. Dr. Anibal Salazar	Yes es	No No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.6 Study #10125 and 10573 (extension)

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Lopes de Santa Maria-33	21	Mr. Dr. Juan Lopez de Santa Maria	Yes Yes Yes Yes Yes Yes	No No No No No No
Orellana-34	19	Mr. Dr. Nelson Orellana	Yes Yes Yes	No No No
GERMANY				
Porst-10	37	Prof. Dr. Hartmut Porst	Yes	No
Ruffer-Hesse-11	9	Dr. Claudia Ruffer-Hesse	Yes Yes Yes Yes	No No No No
Stief-12	12	Prof. Dr. Christian Stief	Yes Yes	No No
Nietzsch-13	36	Dr. Detlev Nietzsch	Yes es	No No
Szymula-14	32	Dr. Silvio Szymula	Yes es	No No
Vilmar-15	36	Dr. Wolfgang Vilmar	Yes	No
Butz-16	19	Prof. Dr. Manfred Butz	Yes	No
Potempa-17	32	Dr. Alex-Jurg Potempa	Yes	No
Grohmann-18	27	Dr. Walther Grohmann	Yes	No
Ernst-19	21	Dr. Gunter Ernst	Yes	No
Von Keitz-20	21	Dr. Alexander von Keitz	Yes	No
Gobel-21	12	Dr. Michael Gobel	Yes	No
Schafer-65	6	Dr. Reinhold Schafer	Yes	No
ISRAEL				
Vardi-58	14	Dr. Yoram Vardi	Yes Yes Yes	No No No
Chen-59	13	Dr. Juza Chen	Yes Yes	No No
Shenfeld-60	8	Dr. Ofer Shenfeld	Yes	No
MEXICO				
Quinzanos-41	16	Dr. Luis Quinzanos	Yes	No
Sotomayor-42	13	Dr. Mariano Sotomayor	Yes Yes Yes	No No No
Ugarte y Romano-43	10	Dr. Fernando Ugarte y		

For explanations of (A), (B), and (C), please see last page of this document.

19.1.6 Study #10125 and 10573 (extension)

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
		Romano	Yes	No
			Yes	No
Pacheco-44	5	Dr. Carlos Pacheco	Yes	No
Gastelum-66	13	Dr. Jorge Jaspersen Gastelum	Yes	No
			Yes	No
			Yes	No
SPAIN				
Cruz-1	13	Dr. Jose Fernando Jimenez Cruz	Yes	No
			Yes	No
			Yes	No
Leiva-3	6	Dr. Oscar Leiva	Yes	No
			Yes	No
Cruz-6	13	Dr. Natalio Cruz	Yes	No
Abal-7	17	Dr. Venancio Chantada Abal	Yes	No
			Yes	No
Vela-64	25	Dr. Luis Rodriguez Vela	Yes	No
			Yes	No
UNITED STATES				
Blank-1	24	Dr. Bruce Blank	Yes	No
Grimm-2	46	Dr. Terrence Grimm	Yes	No
Israeli-3	12	Dr. Ron Israeli	Yes	No
			Yes	No
Jablonski-4	10	Dr. Donald Jablonski	Yes	No
Cochrane-5	59	Dr. James Cochrane	Yes	No
Castellanos-6	35	Dr. Ronald Castellanos	Yes	No
			Yes	No
Wainstein-7	14	Dr. Mark Wainstein	Yes	No
Murdock-8	43	Dr. Myron Murdock	Yes	No
Wells-10	29	Dr. Glen Wells	Yes	No
Shumaker-11	18	Dr. Bryan Shumaker	Yes	No
Moseley-12	41	Dr. William Moseley	Yes	No
Langenstroer-13	7	Dr. Peter Langenstroer	Yes	No
Goldberg-14	52	Dr. Kenneth Goldberg	Yes	No
Smith-15	23	Dr. William Smith	Yes	No
Godschalk-16	19	Dr. M Godschalk	Yes	No
			Yes	No
McKenney-18	38	Dr. James McKenney	Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Bergreen-20	30	Dr. Peter Bergreen	Yes	No
Silbar-28	15	Dr. Elliott Silbar	Yes	No
Sartor-30	8	Dr. Nicholo Sartor	Yes	No
Sliwinski-32	21	Dr. Anthony Sliwinski	Yes	No

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For explanations of (A), (B), and (C), please see last page of this document.

19.1.7 Study #10128 and 10194 (extension)

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
BELGIUM				
Declercq-1	9	Dr. Georges Declercq	Yes	No
Wespes-2	0	Dr. Eric Wespes	Yes	No
Duyck-4	42	Dr. Francis Duyck	Yes	No
Vanderschueren-5	5	Prof. Dirk Vanderschueren	Yes	No
Verheyden-6	0	Dr. Verheyden	Yes	No
DeBruyne-8	3	Dr. Roger DeBruyne	Yes	No
DENMARK				
Gerstenberg-1	5	Dr. Thomas Gerstenberg	Yes	No
Lyngdorf-2	3	Overlaege Peter Lyngdorf	Yes	No
FRANCE				
Giuliano-1	31	Docteur F Giuliano	Yes	No
Buvat-2	53	Docteur J Buvat	Yes	No
Cuzin-3	14	Docteur B Cuzin	Yes	No
Leriche-4	37	Professor Albert Leriche	Yes	No
Bondil-5	11	Docteur Pierre Bondil	Yes	No
Costa-6	19	Professor Pierre Costa	Yes	No
Lebret-7	24	Docteur Thierry Lebret	Yes	No
Blanc-8	4	Docteur Emmanuel Blanc	Yes	No
Lan-9	30	Docteur Olivier Lan	Yes	No
Porto-10	6	Docteur Robert Porto	Yes	No
UK				
Eardley-1	38	Mr. I Eardley	Yes	No
Desai-2	14	Mr. K Desai	Yes	No
Dinsmore-3	90	Dr. W Dinsmore	Yes	No
Kell-4	62	Dr. P Kell	Yes	No
Kirby-5	16	Mr. R Kirby	Yes	No
Speakman-6	11	Mr. M Speakman	Yes	No
Ralph-7	61	Mr. D Ralph	Yes	No
Hackett-8	26	Dr. G Hackett	Yes	No
ITALY				
Montorsi-1	53	Prof. Francesco Montorsi	Yes	No
Mirone-2	26	Prof. Vincenzo Mirone	Yes	No
			Yes	No
Carmignani-3	1-	Prof. Giorgio Carmignani	Yes	No
Fransesca-4	6	Prof. Francesco Fransesca	Yes	No
Menchini-5	27	Prof. Fabris Menchini	Yes	No
Pisani-6	9	Prof. Enrico Pisani	Yes	No
Breda-7	12	Prof. Guglielmo Breda	Yes	No
Belgrano-8	4	Prof. Emanuele Belgrano	Yes	No
Frajese-9	24	Dr. Gaetano Frajese	Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

19.1.7 Study #10128 and 10194 (extension)

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Pagliarulo-10	0	Prof. Arcangelo Pagliarulo	Yes	No
Mirone-11	26	Prof. Vincenzo Mirone	Yes	No
Gentile-12	8	Prof. Vincenzo Gentile	Yes	No
Bonifacio-13	9	Prof. Vincenzo Bonifacio	Yes	No
NETHERLANDS				
Kropman-1	10	Dr. RF Kropman	Yes	No
Meuleman-4	10	Dr. EJM Meuleman	Yes	No
Asscheman-5	9	Dr. H Asscheman	Yes	No
POLAND				
Krajka-1	15	Mr. Prof. Kazimierz Krajka	Yes	No
Borkowski-2	3	Dr. Andrzej Borkowski	Yes	No
SWEDEN				
Dahlstrand-2	2	Doc Christer Dahlstrand	Yes	No
Ekman-4	2	Doc Peter Ekman	Yes	No
Lundquist-7	1	Dr. Bjorn Lundquist	Yes	No

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19.1.8 Study #10232

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
BELGIUM				
Van Renterghem-036	4	K Van Renterghem	Yes	No
Verheyden-037	7	B Verheyden	Yes	No
Oosterlinck-039	8	W Oosterlinck	Yes	No
FRANCE				
Bohbot-046	1	JM Bohbot	Yes	No
Labat-047	6	JJ Labat	Yes	No
Weryha-048	15	G Weryha	Yes	No
Bonierbale-049	9	M Bonierbale	Yes	No
Dujardin-050	13	T Dujardin	Yes	No
Ragni-051	4	E Ragni	Yes	No
Colombel-053	14	MCL Colombel	Yes	No
GERMANY				
Potempa-027	41	AJ Potempa	Yes	No
Potempa-028	10	D Potempa	Yes	No
Albers-030	4	P Albers	Yes	No
Grohmann-031	19	W Grohmann	Yes	No
Porst-032	39	H Porst	Yes	No
Sperling-033	12	H Sperling	Yes	No
Zumbe-034	2	Zumbe	Yes	No
POLAND				
Krajka-056	33	K Krajka	Yes	No
Prajsner-057	14	A Prajsner	Yes	No
Trypens-058	16	P Trypens	Yes	No
Borowka-059	3	A Borowka	Yes	No
Borkowski-060	22	A Borkowski	Yes	No
Bar-061	19	K Bar	Yes	No
Kwias-062	6	Z Kwias	Yes	No
Sikorski-063	12	A Sikorski	Yes	No
SOUTH AFRICA				
Hadders-001	26	CF Hadders	Yes	No
Levinson-002	24	IP Levinson	Yes	No
Grizic-003	51	AM Grizic	Yes	No
Mackenzie-004	38	TM Mackenzie	Yes	No
Haffejee-005	12	M Haffejee	Yes	No
Naude-006	11	JH Naude	Yes	No
Schmidt-007	31	AC Schmidt	Yes	No
Viljoen-008	8	IM Viljoen	Yes	No
Smart-009	17	D Smart	Yes	No
Kassier-010	19	K Kassier	Yes	No
Harden-011	10	PJ Harden	Yes	No
Voss-012	15	S Voss	Yes	No

For explanations of (A), (B), and (C), please see last page of this document.

Site Name and Number	Number of Patients Enrolled	Names of Investigators	Certification and/or Disclosure for each Investigator	Disclosable Information
Coetzee-013	15	L Coetzee	Yes	No
Randaree-014	21	H Randaree	Yes	No
Rencken-015	15	RK Rencken	Yes	No
UK				
McNicholas-017	9	TA McNicholas	Yes	No
Betts-018	8	CD Betts	Yes	No

- (A) Investigator did not enroll any patients and/or no compensation was provided to this investigator by Bayer. Financial Disclosure not available.
- (B) Investigator did not contribute to the study for which the interim report is included in this NDA. Investigator's Financial Disclosure will be submitted with the final report.
- (C) Investigator died – Financial Disclosure not available.

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DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

The following information concerning _____, who participated as a clinical investigator in the submitted study _____, is submitted in accordance with 21 CFR part 54. The named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable checkboxes.

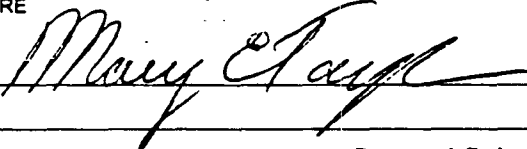
any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

any significant payments of other sorts made on or after February 2, 1999 from the sponsor of the covered study such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

any proprietary interest in the product tested in the covered study held by the clinical investigator;

any significant equity interest as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

NAME Mary Taylor	TITLE Director, Regulatory Affairs
FIRM/ORGANIZATION Bayer Corporation	
SIGNATURE 	DATE September 24, 2001

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