CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 020740

ADMINISTRATIVE DOCUMENTS

EXCLUSIVITY SUMMARY for NDA # 20-740 SUPPL # ____

Trade Name Baycol **Generic Name** cerivastatin tablets
Applicant Name Bayer Corp. **HFD-** 510

Approval Date _____

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 /X/ NO /__/

   b) Is it an effectiveness supplement?

   YES /__/ NO /X/

   If yes, what type? (SE1, SE2, etc.) _____

   c) 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 /X/ NO /__/

   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.

   _____

   _____

   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:

_____

_____

Form OGD-011347 Revised 8/7/95; edited 8/8/95
cc: Original NDA Division File HFD-[redacted] Mary Ann Holovac

d) Did the applicant request exclusivity?

YES /___/ NO /X/

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 ON PAGE 8.

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 /X/

If yes, NDA # _____ Drug Name_____

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /X/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

APPEARS THIS WAY ON ORIGINAL

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2, as appropriate)

1. Single active ingredient product.

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 /X/

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

NDA # _____ _____

NDA # _____ _____

NDA # _____ _____

2. Combination product. N/A

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 /___/

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

NDA # _____ _____

NDA # _____ _____

NDA # _____ _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. 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 ON PAGE 8.

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 /___/

APPEARS THIS WAY
ON ORIGINAL

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval **AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:**

_____
_____

(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 # _____

APPEARS THIS WAY
ON ORIGINAL

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:

NDA # _____ Study #_____
NDA # _____ Study #_____
NDA # _____ Study #_____

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:

NDA # _____ Study #_____
NDA # _____ Study #_____
NDA # _____ Study #_____

APPEARS THIS WAY
ON ORIGINAL

c) 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 #_, Study # _____

Investigation #_, Study # _____

Investigation #_, Study # _____

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

IND # ____ YES /__/ NO /__/ Explain: _____

_____

Investigation #2

IND # ____ YES /__/ NO /__/ Explain: _____

_____

APPEARS THIS WAY ON ORIGINAL

(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 /__/ Explain _____ NO /__/ Explain _____

_____ _____

_____ _____

APPEARS THIS WAY ON ORIGINAL

Investigation #2 !

YES /___/ Explain _____ ! NO /___/ 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: _____

_____

_____

_____

_____ 5/29/97

Signature Date

Title: Chief, Prog Mgmt Staff, DMEDP

_____ 6/4/97

Signature of Division Director Date

APPEARS THIS WAY
ON ORIGINAL

cc: Original NDA Division File HFD-92 Mary Ann Holovac

Section 14

All Investigations relied upon by Bayer in this NDA were conducted by or for Bayer.

DRUG STUDIES IN PEDIATRIC PATIENTS
(To be completed for all NME's recommended for approval)

NDA # 20-740 Trade (generic) names Baycol (cerivastatin) Tablets

Check any of the following that apply and explain, as necessary, on the next page:

____ 1. A proposed claim in the draft labeling is directed toward a specific pediatric illness. The application contains adequate and well-controlled studies in pediatric patients to support that claim.

____ 2. The draft labeling includes pediatric dosing information that is not based on adequate and well-controlled studies in children. The application contains a request under 21 CFR 210.58 or 314.126(c) for waiver of the requirement at 21 CFR 201.57(f) for A&WC studies in children.

____ a. The application contains data showing that the course of the disease and the effects of the drug are sufficiently similar in adults and children to permit extrapolation of the data from adults to children. The waiver request should be granted and a statement to that effect is included in the action letter.

____ b. The information included in the application does not adequately support the waiver request. The request should not be granted and a statement to that effect is included in the action letter. (Complete #3 or #4 below as appropriate.)

____ 3. Pediatric studies (e.g., dose-finding, pharmacokinetic, adverse reaction, adequate and well-controlled for safety and efficacy) should be done after approval. The drug product has some potential for use in children, but there is no reason to expect early widespread pediatric use (because, for example, alternative drugs are available or the condition is uncommon in children).

____ a. The applicant has committed to doing such studies as will be required.

____ (1) Studies are ongoing.
____ (2) Protocols have been submitted and approved.
____ (3) Protocols have been submitted and are under review.
____ (4) If no protocol has been submitted, on the next page explain the status of discussions.

____ b. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

X 4. Pediatric studies do not need to be encouraged because the drug product has little potential for use in children.

____ 5. If none of the above apply, explain.

Explain, as necessary, the foregoing items: _____

Signature of Preparer per M.O.

5-29-97
Date

cc: Orig NDA
HFD-510/Div File
NDA Action Package

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 020740

CORRESPONDENCE

Bayer

Pharmaceutical Division

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175

July 2, 1996

Solomon Sobel, M.D., Director
Division of Metabolism and Endocrine Drug Products
Office of Drug Evaluation II, HFD-510
Center for Drug Evaluation and Research
Food and Drug Administration
Att: Document Control Room 14B-04
5600 Fisher Lane
Rockville, Maryland 20857

Re: **NDA 20-740**
Baycol (Cerivastatin) Tablets

Dear Dr. Sobel:

Bayer Corporation Pharmaceutical Division hereby certifies under Section 306 (k) of the act (21 USC a (k) (1)) that it did not and will not use in any capacity the services of any person debarred under subsections (a) or (b) {section 306 (a) or (b)}, in connection with this NDA.

If there any questions regarding this submission, please contact me at (203) 812-2615.

Sincerely,

Nancy C. Motola, Ph.D.
Deputy Director, Regulatory Affairs

NCM/do/02

APPEARS THIS WAY
ON ORIGINAL

cc: Julie Rhee, CSO
Gene Simonalle

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Expiration Date: ... See OMB Statement on Page 3.

FOR FDA USE ONLY	
DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314)*.

NAME OF APPLICANT	DATE OF SUBMISSION
Bayer Corporation Pharmaceutical Division	June 26, 1996
ADDRESS *(Number, Street, City, State and ZIP Code)*	TELEPHONE NO. *(Include Area Code)*
400 Morgan Lane West Haven, CT 06516-4175	(203) 812-2615
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER *(If previously issued)*
	NDA 20-740

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(If any)*
cerivastatin	

CODE NAME *(If any)*	CHEMICAL NAME
BAY w 6228	Sodium [S-[R*,S*-(E)]]-7-[4-(4-fluorophenyl)-5-methoxymethyl)-2,6bis(1-methylethyl)-3-pyridinyl] -3,5-dihydroxy-6-heptenoate

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTHS(S)
Tablet	Oral	50 ug 100 ug 200 ug 300 ug

PROPOSED INDICATIONS FOR USE

Hypercholesterolemia

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21 CFR 314.420)* REFERRED TO IN THIS APPLICATION:

INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☒ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) *(21 CFR 314.55)*

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☒ AN AMENDMENT TO A PENDING APPLICATION ☐ SUPPLEMENTAL APPLICATION

☐ ORIGINAL APPLICATION ☐ RESUBMISSION

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION *(e.g., Part 314.70(b)(2)(iv))* _____

PROPOSED MARKETING STATUS *(Check one)*

☐ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

NDA 20-740

AUG - 1 1996

Bayer Corporation Pharmaceutical Division
Attention: Nancy C. Motola, Ph.D.
Deputy Director, Regulatory Affairs
400 Morgan Lane
West Haven, Connecticut 06516-4175

Dear Dr. Motola:

Please refer to your pending new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Baycol (cerivastatin) Tablets.

We have had the filing meeting for this NDA and it will be filed on August 25, 1996. However, we have the following comments and information requests:

Biopharmaceutics:

1. You submitted dissolution profiles using Since is relatively fast for , the dissolution profiles at should be submitted in t

2. Cerivastatin sodium will be administered as a pure enantiomer. However, no information was provided in the June 26, 1996, submission (Section 6) to indicate whether or not there is in vivo chiral inversion in humans. Please provide information.

3. We strongly encourage you to conduct PK/PD (efficacy and safety endpoints) analyses as well as covariate analyses for Study D91-031 (a pivotal US clinical trial) and to submit the results as soon as possible.

4. All raw data for individual study should be sent to the Agency in diskettes as ASCII files and the human pharmacokinetics summary (volume 1.90) as WorldPerfect version 6.1.

Biometrics:

1. Volume numbers as well as page numbers should be included on the Table of Contents for each of the three pivotal trials. Please provide a revised Table of Contents which includes the volume and page numbers.

2. Volume numbers and page numbers should be added to the Tables and Figures listing for each of the three pivotal trials. Please submit this information. Also, in the future, please integrate the important tables and figures into the text.

We would appreciate your prompt written response.

If you have any questions, please contact Ms. Julie Rhee, Consumer Safety Officer, at (301) 443-3510.

Sincerely yours,

8-1-96

Solomon Sobel, M.D.
Director
Division of Metabolic and
Endocrine Drug Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:OrigNDA
HFD-510/DivFile
HFD-870/HAhn
HFD-715/JMele
HFD-511/JRhee
R/D by: JRhee 7-29-96
Concurrence: EGalliers 7-29-96/HAhn 7-31-96/JMele 8-1-96 8-1-96
F/T by: JRhee 8-1-96

Information Request/Advice

NDA 20-740

JUL - 2 1996

Bayer Corporation Pharmaceutical Division
Attention: Nancy C. Motola, Ph.D.
Deputy Director, Regulatory Affairs
400 Morgan Lane
West Haven, Connecticut 06516-4175

Dear Dr. Motola:

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

Name of Drug Product: Baycol (cerivastatin)
50, 100, 200, and 300 µg Tablets

Therapeutic Classification: Standard

Date of Application: June 26, 1996

Date of Receipt: June 26, 1996

Our Reference Number: NDA 20-740

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on August 25, 1996, in accordance with 21 CFR 314.101(a).

Under 21 CFR 314.102(c) of the new drug regulations and in accordance with the policy described in the Center for Drug Evaluation and Research Staff Manual Guide CDER 4820.6, you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the application's ultimate approvability. Please request the meeting at least 15 days in advance. Alternatively, you may choose to receive such a report by telephone. Should you wish a conference, a telephone report, or if you have any questions concerning this NDA, please contact:

Ms. Julie Rhee
Consumer Safety Officer
(301) 443-3510

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely yours,

7-2-96

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and
Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc
Orig. NDA
HFD-510/DivFile
HFD-511/JRhee
HFC-130/DISTRICT OFFICE
R/D by: JRhee 7-1-96 c:wpfiles/letter/n20740.ack
Concurrence: Galliers 7-1-96
F/T by: JRhee 7-2-96

ACKNOWLEDGEMENT - AC

RECORD OF TELEPHONE CONVERSATION/MEETING	Date: July 1, 1996
Re: June 26, 1996 submission I called Dr. Motola and asked the following: 1. Debarment certification The original NDA submission did not include Debarment Certification. I explained to her that NDA application submitted after 1992 has to include a statement that they did not and will not use, in any capacity, the services of any debarred under Section 306(a) or (b) of the Act. Dr. Motola agreed to provide the certification next week. 2. Desk copy for Environmental Assessment I asked her if it is possible for me to have a desk copy for EA by tomorrow. Dr. Motola said she'll try. cc:OrigNDA HFD-510/DivFile HFD-511/JRhee	**NDA#: 20-740** **Telecon./Meeting initiated by:** ○ Applicant/Sponsor ● FDA **By:** Telephone **Product Name:** Baycol (cerivastatin) Tablets **Firm Name:** Bayer Corporation West Haven, CT **Name and Title of Person with whom conversation was held:** Nancy Motola, Ph.D. Deputy Director, Regulatory Affairs **Phone:** (203) 812-2615
Name: Julie Rhee	

RECORD OF TELEPHONE CONVERSATION/MEETING	DATE: 5/23/97
A T-Con took place: Date: 5/23/97 Time: 11:30 - 11:50 Place: Pkln - 1456 Members: FDA A. Dr. Karl Lin B. Dr. Baldeo Toneja C. Margaret Simoneau Members: Bayer A. Dr. Eberhard Karbe A telephone conference was set for 0945 by Dr. Motola of Regulatory Affairs with Wolfgan Rossberg in Germany to clarify the May 22, 97 fax. Dr. Rossberg was suppose to call the FDA for this telephone conference. Dr. Motola informed us he failed to call after numerous attempts to contact him in Germany. A second conference this day was made with an Eberhard Karbe, who informed us he was **not** a statistician and could not answer our questions and requested another telephone conference on Tuesday, 27 May 97 at 9 a.m. Conclusion: He was specifically asked to: 1. Please compute p-values following the same procedure for carcinomas plus multiple carcinomas, as on p. 5 of computer printout that was faxed on May 22, 1997. 2. What does "PERIOD" mean on p.4 of computer printout that faxed on May 22, 1997. Please explain the numbers 37,544 and 598 under PERIOD in the last column. cc: Original NDA HFD-510/Div. Files Margaret Simoneau Name: Margaret Simoneau	**NDA: 20-740** **Telephone Conference** **Initiated by:** ■ Applicant/Sponsor □ FDA **By:** Telephone **Product Name:** Baycol **Firm Name:** Bayer **Name and Title of Person with whom conversation was held:** **Phone:** 202-36-85-68 Germany

RECORD OF TELEPHONE CONVERSATION/MEETING	DATE: 5/21/97
A T-Con took place: Date: 21 May 97 Time: 0845-0905 Place: Pkln-1456 Members: FDA A. Dr. Karl Lin B. Dr. Baldeo Taneja C. Margaret Simoneau, RPh Members:Bayer A. Nancy Motola, PhD B. Dr. Harry Olson Discussion: FDA REQUESTED 1. Clarification of Enclosure (1) 2. Definition of time interval used 3. Want PETO analysis to calculate "P" values Result: Bayer requests information from Germany. FDA will get response by 23 May 97. cc: Original NDA HFD-510/Division files Margaret Simoneau Name: Margaret Simoneau	**NDA: 20-740** **Telephone Conference** **Initiated by:** ☐ Applicant/Sponsor ■ FDA **By:** Telephone **Product Name:** ~~Bayer~~ Bayer **Firm Name:** Bayer **Name and Title of Person with whom conversation was held:** Nancy Motolo **Phone:** 203-812-2615

C