# CENTER FOR DRUG EVALUATION AND RESEARCH

***BLA APPLICATION NUMBER:***

**125156**

# ADMINISTRATIVE / CORRESPONDENCE DOCUMENTS

**MEMORANDUM**

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

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# CLINICAL INSPECTION SUMMARY

DATE: June 28, 2006

TO: Lori Gorski, Regulatory Project Manager
Rhea Lloyd, M.D., Title, Clinical Reviewer
Division of Anti-Infective and Ophthalmology Products, HFD-550

THROUGH: Leslie K. Ball, M.D.
Branch Chief
Good Clinical Practice Branch 2, HFD-47
Division of Scientific Investigations

FROM: Mathew T. Thomas, MD., Pharmacologist

SUBJECT: Evaluation of Clinical Inspections

BLA: 125156

NME: Yes

APPLICANT: Genentech

DRUG: ranibizumab (Lucentis)

THERAPEUTIC CLASSIFICATION: Priority

INDICATION: Treatment [redacted] of neovascular age-related macular degeneration.

CONSULTATION REQUEST DATE: May 8, 2006

DIVISION ACTION GOAL DATE: June 30, 2006

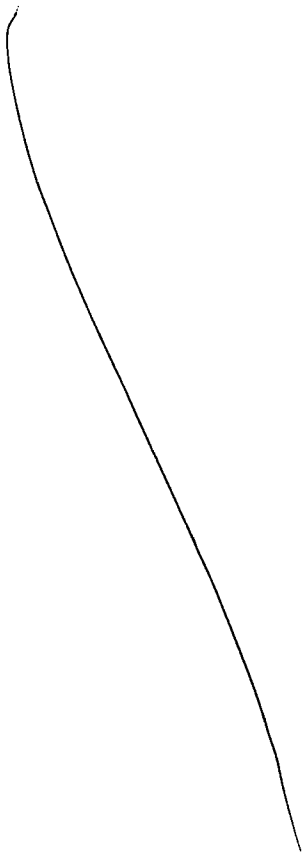
PDUFA DATE: June 30, 2006

## I. BACKGROUND:

On May 8, 2006, the Review Division issued a consult to DSI for inspecting __study sites involved in two study protocols (#s FVF2587g and FVF2598g) from which data were submitted in support of BLA 125526. The PDUFA date for this BLA was June 30, 2006. The BLA was for ranibizumab injection (Lucentis) for the treatment ——— of neovascular age-related macular degeneration.

The review division did not have any specific concerns about the data from any of the study sites in the BLA. ⌐

⌜ ⌝



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*Withheld Track Number: Administrative-* 1 of 6

An inspection summary addendum will be generated if conclusions change upon receipt and review of the EIRs.

Mathew T. Thomas, MD
Pharmacologist

CONCURRENCE:

Supervisory comments

Leslie K. Ball, M.D.
Branch Chief
Good Clinical Practice Branch II
Division of Scientific Investigations

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## Gorski, Lori M

**From:** Harper Velazquez, Tia M
**Sent:** Monday, June 19, 2006 10:19 AM
**To:** Gorski, Lori M
**Subject:** FW: Compliance Check for BLA 125156/0

Hi Lori - forwarding this for the action packet for BLA 125156/0. Thanks. Tia

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***Tia M. Harper-Velazquez, Pharm.D.***
***Lt. Commander, USPHS***
***Project Manager***
***Office of Compliance, HFD-300***
***Phone: 301-827-8995 (MM2)***
***Phone: 301-443-5140 (Rockwall 2)***
***Fax: 301-443-5245***


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**From:** Ferguson, Shirnette D
**Sent:** Friday, June 16, 2006 11:15 AM
**To:** Hughes, Patricia
**Cc:** CDER-TB-EER; Harper Velazquez, Tia M
**Subject:** FW: Compliance Check for BLA 125156/0

The Investigations and Preapproval Compliance Branch has completed the review and evaluation of the Therapeutic Biologic-EER request below. There are no pending or ongoing compliance actions to prevent approval of STN 125156/0 at this time.

The following is the current status for the submitted sites:

| Manufacturer | FEI # | Profile Class | Profile Status | EIR Classification |
|---|---|---|---|---|
| [redacted] | | | | |

Shirnette

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**From:** Cruz, Concepcion
**Sent:** Friday, June 16, 2006 10:06 AM
**To:** Ferguson, Shirnette D
**Subject:** FW: Compliance Check for BLA 125156/0

F → F [aka Friday to Ferguson]

Coki Cruz

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**From:** Hughes, Patricia
**Sent:** Friday, June 16, 2006 10:05 AM
**To:** CDER-TB-EER
**Cc:** Harper Velazquez, Tia M; Uratani, Brenda W; Clark-Stuart, Michelle; Cruz, Concepcion
**Subject:** Compliance Check for BLA 125156/0

Please complete a compliance check in support of a new BLA for the two drug product manufacturing sites listed below (under Manufacturing Facilities for drug product):

plication - BLA: STN 125156/0 from Genentech, Inc., South San Francisco
oduct: Lucentis (ranibizumab)
Indication: Treatment of neovascular age-related macular degeneration
Manufacturing Facilities for drug product:

PDUFA Date: 01 July 2006

Thank you.

Patricia

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*Withheld Track Number: Administrative-* 4026

**CONSULTATION RESPONSE**

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT**
**OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY**
**(DMETS; White Oak 22, Mail Stop 4447)**

| **DATE RECEIVED:** August 11, 2005<br>**DOCUMENT DATE:** August 3, 2005 | **DESIRED COMPLETION DATE:** October 11, 2005<br>**PDUFA DATE:** June 30, 2006 | **OSE CONSULT #:** 05-0211 |
|---|---|---|

**TO:** Janice Soreth, M.D.
Director, Division of Anti-Infective and Ophthalmology Products
HFD-520

**THROUGH:** Linda Y. Kim-Jung, Pharm.D., Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, R.Ph., Director
Division of Medication Errors and Technical Support

**FROM:** Todd D. Bridges, R.Ph., Safety Evaluator
Division of Medication Errors and Technical Support

| **PRODUCT NAME:**<br>**Lucentis**<br>(Ranibizumab Injection)<br>0.5 mg/0.05 mL<br><br>**LA #:** 125156 (**IND #:** — | **SPONSOR:** Genentech |
|---|---|

**RECOMMENDATIONS:**

1. DMETS has no objections to the use of the proprietary name, Lucentis. DMETS considers this a final review. However, if approval of the application is delayed beyond 90 days from the signature date of this review then the name and its labels and labeling must be re-evaluated. A re-review of the name prior to BLA approval will rule out any objections based upon approvals of other proprietary or established names from the signature date of this document.

2. DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review in order to minimize potential errors with use of this product.

**Division of Medication Errors and Technical Support**
**Office of Surveillance and Epidemiology**
**WO 22, MAIL STOP 4447**
**Center for Drug Evaluation and Research**

**PROPRIETARY NAME REVIEW**

**DATE OF REVIEW:** September 15, 2005

**BLA #:** 125156 (IND #: ——

**NAME OF DRUG:** **Lucentis**
(Ranibizumab Injection)
0.5 mg/0.05 mL

**IND SPONSOR:** Genentech

## I. INTRODUCTION

This consult was written in response to a request from the Division of Anti-Infective and Ophthalmology Products (HFD-520), for assessment of the proprietary name, Lucentis, regarding potential name confusion with other proprietary or established drug names. Container labels, carton and insert labeling were submitted for review and comment. Additionally, the sponsor submitted an independent name analysis prepared by ——— , for review and comment.

PRODUCT INFORMATION

Lucentis is an angiogenesis inhibitor indicated for treatment of the wet form of age-related macular degeneration. The recommended dose is 0.5 mg administered intravitreally once every month. Lucentis, which will require refrigeration, will be supplied as a —— single-dose vial and packaged with a filter needle and a needle for injection.

## II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts[i,ii] as well as several FDA databases[iii,iv] for existing drug names which sound-alike or look-alike to ——— to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted[v]. The SAEGIS[vi] Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three

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[i] MICROMEDEX Integrated Index, 2005, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.
[ii] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, Missouri.
[iii] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-05, and the electronic online version of the FDA Orange Book.
[iv] Phonetic and Orthographic Computer Analysis (POCA)
[v] www location http://www.uspto.gov/tmdb/index.html.
[vi] Data provided by Thomson & Thomson's SAEGIS™ Online service, available at www.thomson-thomson.com

prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

A. EXPERT PANEL DISCUSSION

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Lucentis. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

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2. The Expert Panel identified two proprietary names which were thought to have the potential for confusion with Lucentis. This products are listed in Table 1 (see page 4), along with the dosage forms available and usual dosage.

Table 1. Potential Sound-Alike/Look-Alike Names Identified for Lucentis.

| Product Name* | Dosage form (route) and strength of proposed name | [illegible] | Other** |
|---|---|---|---|
| Lucentis | Ranibzumab<br>0.5 mg solution for injection | [illegible] | N/A |
| Lantus | Insulin glargine<br>100 units/mL solution for injection | Individualized dose given subcutaneously. | LA,SA |
| Lunesta | Eszopiclone<br>1 mg, 2 mg, 3 mg tablets | 1 mg to 3 mg immediately before bedtime. | LA |

*Frequently used, not all-inclusive.
**LA (look-alike), SA (sound-alike)

B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Lucentis with other U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. These studies employed a total of 119 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Lucentis (see page 5). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail messages were then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

| HANDWRITTEN PRESCRIPTION | VERBAL PRESCRIPTION |
|---|---|
| Outpatient RX:<br>Lucentis<br>#1<br>Use every four weeks as directed | Lucentis<br>#1<br>Use every four weeks as directed |
| Inpatient RX:<br>Lucentis use every 4 weeks as directed | |

2. Results:

   None of the interpretations of the proposed name overlap, sound similar, or look similar to any currently marketed U.S. product. See Appendix A (page 15) for the complete listing of interpretations from the verbal and written studies.

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Lucentis, the primary concerns relating to look-alike and sound-alike confusion with Lucentis are Lantus and Lunesta.

Additionally, DMETS conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that the proposed name could be confused with any of the aforementioned names. However, negative findings are not predicative as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to a small sample size. The majority of misinterpretations were misspelled/phonetic variations of the proposed name, Lucentis.

Upon further review of the names gathered from EPD, the name Lantus will not be discussed further due to a lack of convincing look-alike and sound-alike similarities with Lucentis in addition to differentiating product characteristics such as the product strength, indication for use, frequency of administration, and route of administration.

Lunesta was identified as a name with similar appearance to Lucentis when scripted. Lunesta is a nonbenzodiazepine hypnotic agent indicated for the treatment of insomnia characterized by difficulty falling asleep, and/or difficulty maintaining sleep during the night and early morning. The usual dose is 1 mg to 3 mg immediately before bedtime. Lunesta is available as 1 mg, 2 mg, and 3 mg tablets.

Both names begin with the same two letters ("Lu") and each name has the upstroke letter "t" as the sixth letter which contributes to the visual similarity of this name pair. However, the middle letters ("cen" vs. "nes") and endings ("is" vs. "a") of each name may help to orthographically differentiate Lucentis from Lunesta on an order (see writing sample below). Lunesta is available in three different strengths and thus, the product strength must either be indicated on a prescription or obtained from the prescriber prior to dispensing which may further differentiate this name pair. The necessity for strength on a prescription written for Lunesta will help to decrease the potential for confusion between this name pair. Furthermore, Lucentis and Lunesta have different dosing regimens (once every month or once every month for 3 consecutive doses followed by a dose administered once every 3 months vs. once daily at bedtime), dosage formulation (solution for injection vs. tablet), prescriber population (ophthalmologist vs. primary-care physician), dose (0.5 mg vs. 1 or 2 tablets), and route of administration (intravitreally vs. orally). The ordered quantity for Lucentis and Lunesta will likely differ as well (e.g., #1 vs. #30). The ordered net quantity, if included on a prescription order, may help to differentiate these products. Furthermore, while an order for Lucentis may be written with the instructions "use as directed", an order for Lunesta will likely be written with a specific dose and frequency of administration (e.g., 1 tab. hs or 2 mg hs) and unlike Lunesta, Lucentis will not be available in retail pharmacies as it is intended to only be administered by a physician. The differing product characteristics described above, including the non-retail distribution of Lucentis, will help to minimize the potential for confusion between the two drug products.

Lunesta
Lucentis

D. INDEPENDENT NAME ANALYSIS

The sponsor employed [redacted] to conduct an independent analysis of the proposed proprietary name, Lucentis. The sponsor submitted an updated report from [redacted] which is based on the original research study conducted in March 2003, as well as an abbreviated review (i.e., Gap Analysis) of Lucentis conducted in April 2005, by the [redacted]). Also forwarded to DMETS by the Division of Review Management and Policy are the executive summary and addendum to a trademark safety evaluation of Lucentis performed for Genentech by [redacted] in May 2005.

1. [redacted]

a. Similar drug name listing

One hundred physicians were asked to view the proposed proprietary name, Lucentis, and list any existing brand or generic drug names that might be considered similar, based on sound and/or appearance. The following two names were listed as being similar to Lucentis: Lotrel and Lumigan.

***DMETS Response:***

Lotrel and Lumigan were not identified by DMETS as having the potential for confusion with Lucentis. DMETS agrees with [redacted], that neither of these names pose a significant safety risk due to numerous differentiating product characteristics such as product strength, indication for use, frequency of administration, route of administration, dosage formulation, and/or storage condition.

b. Medical term similarity

One hundred physicians were asked to identify any medical term that might be considered similar to the proposed proprietary name, Lucentis, based on sound and/or appearance. No terms were identified.

***DMETS Response:***

DMETS acknowledges the findings for Lucentis.

c. Exaggerative/inappropriate name identification

One hundred physicians were asked to identify any hyperbole or false claims implied by the proposed name, Lucentis. The following table lists participant responses for this inquiry.

Table 2. Responses from inquiry regarding the name Lucentis as exaggerative/inappropriate.

| Number | Response | Percentage |
|---|---|---|
| 98 | No issues | 98% |
| 1 | Implies clarity | 1% |
| 1 | Suggests intraocular lens | 1% |
| 100 | Total | 100% |

***DMETS Response:***

[redacted]

d. Written and verbal order interpretation

One hundred actively practicing institution-based pharmacists listened to verbal medical orders for Lucentis from physicians and then gave their interpretation of what was heard. Additionally, after being shown handwritten medical orders for Lucentis from physicians, these one hundred pharmacists gave their interpretation of what was viewed. In both of these studies, it is reported that pharmacists did not misinterpret Lucentis for any marketed drug products.

***DMETS Response:***

DMETS acknowledges the findings. However, negative study findings are not predictive as to what may occur once Lucentis is widely prescribed, as these studies have limitations primarily due to a small sample size.

e. Computer assisted analysis

A search of medical references was conducted to identify any drug names that might be considered similar to the proposed proprietary name, Lucentis, based on sound and/or appearance. This research identified twelve names which are listed in Table 3 below.

Table 3. Potential look-alike/sound-alike names for Lucentis as identified by search of medical references.

| | |
|---|---|
| Centvites | Leucine |
| Glucerna | Licetrol |
| Lactinol | Licorice |
| Lanatuss | Lotrel |
| Lantus | Lumigan |
| Lentinan | Lunelle |

***DMETS Response:***

With the exception of Lantus, DMETS did not identify any of the other names as having look-alike and/or sound-alike similarities with Lucentis. However, following review of these names, DMETS agrees with [redacted] that none of these names pose a significant safety risk due to numerous differentiating product characteristics such as product strength, indication for use, frequency of administration, route of administration, dosage formulation, and/or storage condition.

f. Full name screening for similar medical terms

A review of the medical terms, acronyms, and abbreviations identified indicates no apparent issues for the communication of proposed proprietary name, Lucentis, in medical settings.

***DMETS Response:***

DMETS does not consider any of these medical terms, acronyms, or abbreviations as having a risk for confusion with Lucentis.

g. Gap analysis - Internal expert panel discussion (EPD)

The [redacted] identified the following names, approved March 3, 2003 through April 25, 2005, as being potentially similar to Lucentis: Levitra, Lunesta, Luveris, and Luxacor.

***DMETS Response:***

With the exception of Lunesta, which is evaluated in Section II of this review, DMETS did not identify any of the other names as having look-alike and/or sound-alike similarities with Lucentis. However, following review of these names, DMETS concurs with ~~~~ that none of these names pose a significant safety risk due to numerous differentiating product characteristics such as product strength, indication for use, frequency of administration, route of administration, dosage formulation, and/or storage condition.

h. Computerized orthographic phonologic analysis (COPA)

The drug names Lunesta and Luveris showed increased similarity with Lucentis by exceeding the COPA threshold value for combined similarity, while the drug names Plenaxis and Ventavis showed increased similarity with Lucentis by exceeding the COPA threshold value for orthographic similarity only. No drug products showed increased sound-alike similarity with Lucentis by exceeding the COPA threshold value for phonetic measurement.

***DMETS Response:***

With the exception of Lunesta, which is evaluated in Section II of this review, DMETS did not identify any of the other names as having look-alike and/or sound-alike similarities with Lucentis. However, following review of these names, DMETS concurs with ~~~~ that none of these names pose a significant safety risk due to numerous differentiating product characteristics such as product strength, indication for use, frequency of administration, route of administration, dosage formulation, and/or storage condition.

i. DSI-reference comparative safety analysis

The following products were identified in the Gap Analysis as sharing two or more commonalities with Lucentis: Macugen, Octagam, Tysabri, and Vidaza. None of the COPA thresholds for orthographic, phonetic, or combined similarity were exceeded for any of these four products, indicating diminished potential for confusion with Lucentis in the marketplace.

***DMETS Response:***

Although these products have some overlapping product characteristics, the names lack convincing orthographic and phonetic similarities. DMETS concurs with ~~~~ that the potential for confusion between these names and Lucentis is limited.

2. [redacted]

a. Table I – Look-alike names with potential for confusion

[redacted] identified the following two names as being mentioned by respondents and evaluated by [redacted] staff as having the potential for look-alike confusion when handwritten: Lantus and Lunesta.

***DMETS Response:***

Lantus and Lunesta were identified by DMETS as having the potential for look-alike confusion with Lucentis. The name Lunesta is evaluated in Section II of this review. Lantus was not reviewed further by DMETS due to a lack of convincing look-alike similarities with Lucentis in addition to differentiating product characteristics.

b. Table II – Sound-alike names with potential for confusion

[redacted] did not identify any names that were mentioned by the respondents that had the potential for sound-alike similarities to Lucentis.

**DMETS Response**:

DMETS acknowledges the findings for Lucentis.

c. Table III – Medical terms with potential for confusion

[redacted] did not identify any medical terms with potential for confusion with Lucentis.

**DMETS Response**:

DMETS acknowledges the findings for Lucentis.

d. Table IV – Respondents' suitability comments (rating) of proposed trademark

[redacted] identified the following remarks from the respondents: "sounds evil" and "too close to Aventis".

**DMETS Response**:

DMETS acknowledges the comments regarding the suitability of the name Lucentis.

e. Table V – FDA and USAN Regulatory Assessment

[redacted] presented evaluation criteria drawn from the paper "Avoiding Trademark Trouble at FDA", which was published in the June 1996 issue of Pharmaceutical Executive.

**DMETS Response**:

DMETS cannot comment on the regulatory assessment provided by . ——— The paper quoted was published in June 1996 and is not currently used by DMETS to evaluate tradenames.

f. Addendum to the Trademark Safety Evaluation of Lucentis

Luveris and Lucentis can safely coexist in the marketplace.

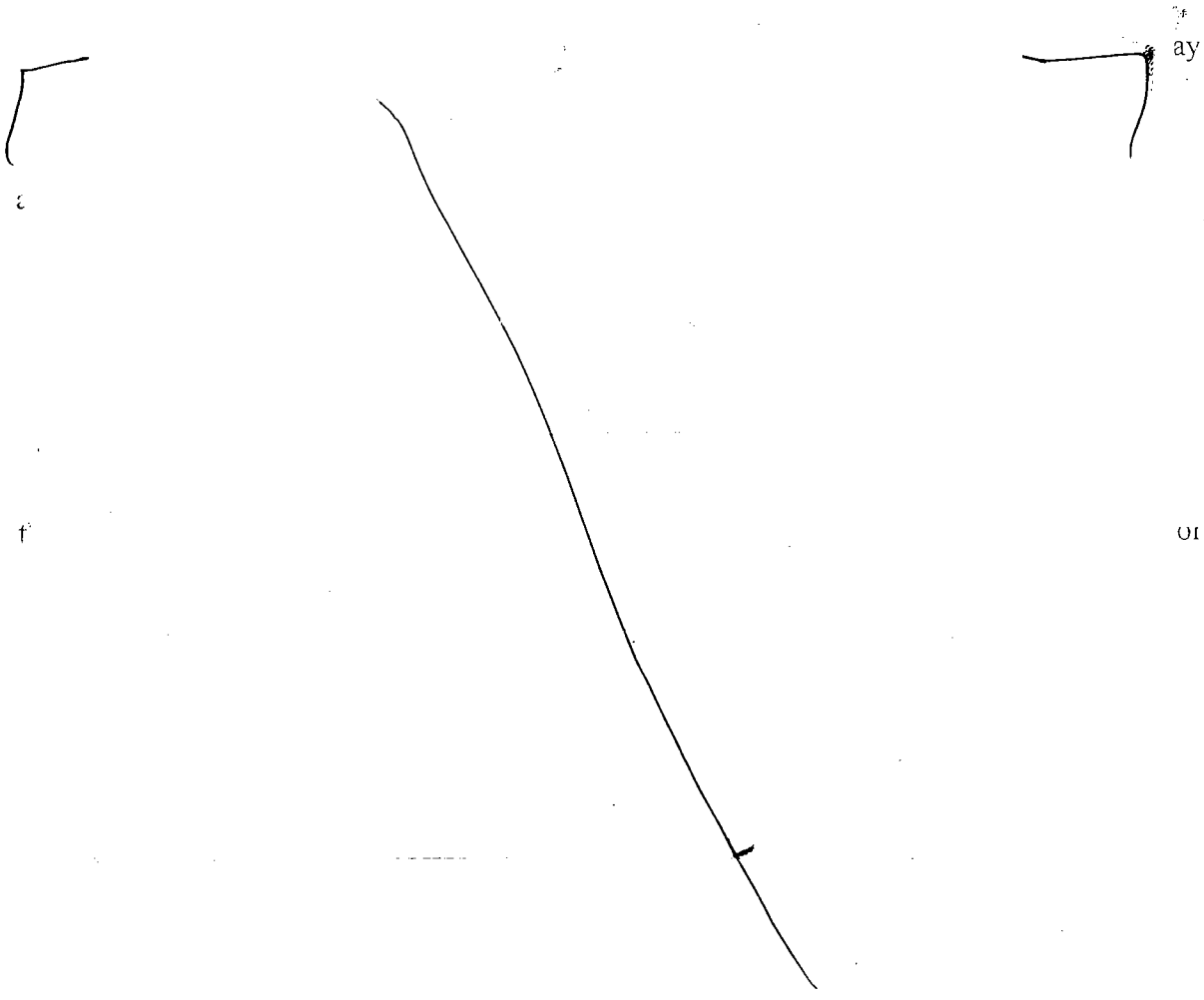
**DMETS Response:**

DMETS agrees with ——— that Luveris does not pose a significant safety risk.

## III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

In the review of the container labels, carton and insert labeling of Lucentis, DMETS has attempted to focus on safety issues relating to possible medication errors. DMETS has identified several areas of possible improvement, which might minimize potential user error.

1. GENERAL COMMENTS



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Appendix A. DMETS prescription study results for Lucentis.

| Voice | Inpatient | Outpatient |
|---|---|---|
| Licenta | Lucentis | lucenta |
| Lisenta | Lucentis | Lucentis |
| Lisentis | Lucentis | Lucentis |
| Lisentis | Lucentis | Lucentis |
| Lisintus | Lucentis | Lucentis |
| Lucentis | Lucentis | Lucentis |
| Lucentis | Lucentis | Lucentis |
| Lucentis | Lucentis | Lucentis |
| Lucentis | Lucentis | Lucentis |
| Lucentis | Lucentis | Lucentis |
| Lucentis | Lucentis | Lucentis |
| Lucinta | Lucentis | Lucentis |
| Lysintus | Lucentis | Lucentis |
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*Withheld Track Number: Administrative-*_____

## LICENSING ACTION RECOMMENDATION

**Applicant:** Genentech, Inc BLA #: 125156/0

**Product (established and proprietary names):**

Ranibizumab

**Indication / manufacturer's change:**

Neovascular age-related macular degeneration

☐ Approval Action:
- ☐ Summary Basis For Approval (SBA) included; or
- ☐ SBA-equivalent reviews included

☐ Other Final Action:
- ☐ Refusal to File: Memo included
- ☐ Denial of application / supplement: Memo included

### CLEARANCE – FDA PRODUCT RELEASE

☐ FDA Lot release not required

☐ Lot no.(s) in support – not for release _____

☐ Lot no.(s) for release _____

Director, Product Release Branch _____

### RECOMMENDATION BASIS

☐ Review of Documents (e.g. listed on Licensed Action Recommendation Report)

☐ Inspection of establishment ☐ Inspection report included

☐ DSI BiMo inspections completed ☐ DSI BiMo report included

☐ Review of protocols for lot no.(s) _____

☐ Test Results for lot no.(s) _____

☐ Review of Environmental Assessment ☐ FONSI included ☐ Categorical Exclusion

☐ Review of labeling Date completed _____ ☐ None needed

### CLEARANCE – REGULATORY REVIEW

☐ Compliance status checked ☐ Acceptable ☐ Hold Date: _____

☐ Cleared from Hold Date: _____

☐ Compliance status check Not Required

Regulatory Project Manager (RPM) _____ Date: _____

### CLEARANCE – SCIENTIFIC REVIEW

Responsible Team Leader: _____ Date: 6/22/06

Responsible Division Director Kathleen A. Clouse Date: 6/26/06

Form: LARM (CDER – 08/2005)

# *RMS/BLA - Product Information Sheet for TBP*

**STN:** 125156/ 0 **Reg. Coordinator:** Lori Gorski

Document Date: _____ FDA Rcvd Date: _____ CBER Rcvd Date: _____

Applicant Genentech

Product ranibizumab for injection

Proprietary/Trade Name(s) Lucentis

**Complete a box for each indication**

**Indication** neovascular (wet) age-related macular degeneration

**Dose** 0.5 mg

**Age groups** - check all that apply

☒ Adult 18+ ☐ All ☐ Child 3-12 ☐ Geriatric 65+ ☐ Pediatric 0-3 ☐ Young Adult 13-18 ☐ Other _____

**Indication Product Use** - check all that apply

☐ Ancillary ☐ Diagnostic/Therapeutic ☐ Therapeutic ☐ Prophylaxis ☐ Other _____

☐ Further Manufacturing Injectable ☐ Further Manufacturing Non Injectable

---

**Indication** _____

**Dose** _____

**Age groups** - check all that apply

☐ Adult 18+ ☐ All ☐ Child 3-12 ☐ Geriatric 65+ ☐ Pediatric 0-3 ☐ Young Adult 13-18 ☐ Other _____

**Indication Product Use** - check all that apply

☐ Ancillary ☐ Diagnostic/Therapeutic ☐ Therapeutic ☐ Prophylaxis ☐ Other _____

☐ Further Manufacturing Injectable ☐ Further Manufacturing Non Injectable

---

**Guidance for completion of this form**

Indication/Usage -- As stated in the P.I. This should also go into the short summary under the submission screen

Dose – From the "Dosage and Administration" section of P.I. - This is what the patient actually gets.

Dosage/Physical Form Details – From the "How Supplied" section of P.I. - Enter final dosage strengths; Potency & Units are important for user fee information

# *Product Information Sheet - Dosage/Physical Form*

***Complete one sheet for each physical form, potency, and fill size.***

**STN:** 125156/ 0 **Reg. Coordinator:** Lori Gorski

**Dosage/Physical Forms** injectable solution (See back page for Valid Values)

**Dosage**

**Potency** (measurement of activity or strength) 10 **Units** mg/ml (See back page for Valid Values)

**Duration** (length of time dosage will remain stable) 18 (months)

**Temperature** 2-8 °C

**Container Type**

☐ Ampule (Glass) ☐ Ampule (Plastic) ☐ Bag Bulk ☐ Bottle ☐ Pump Spray

☐ Other** _____ ☐ Syringe ☐ Tube ☒ Vial

**Container Closure**

☐ Heat Seal ☐ Plunger ☐ Screw Cap Closure ☐ Stopper (Dry Natural Rubber)

☒ Stopper (Synthetic) ☐ Stopper (Unknown) ☐ Other

**Container Fill Size** ___ 1 (Volume)

**Route of Administration** intravenal (See back page for Valid Values)

---

**Dosage/Physical Forms** _____ (See back page for Valid Values)

**Dosage**

**Potency** (measurement of activity or strength) _____ **Units** _____ (See back page for Valid Values)

**Duration** (length of time dosage will remain stable) _____ (months)

**Temperature** _____

**Container Type**

☐ Ampule (Glass) ☐ Ampule (Plastic) ☐ Bag Bulk ☐ Bottle ☐ Pump Spray

☐ Other** _____ ☐ Syringe ☐ Tube ☐ Vial

**Container Closure**

☐ Heat Seal ☐ Plunger ☐ Screw Cap Closure ☐ Stopper (Dry Natural Rubber) ☐ Stopper (Synthetic)

☐ Stopper (Unknown) ☐ Other

**Container Fill Size** _____ (Volume)

**Route of Administration** _____ (See back page for Valid Values)

# *Product Information Sheet - Dosage/Physical Form*

## *Listing of Valid Values*

### Dosage/Physical Forms

- ☐ Inhalant Solution
- ☒ Injectable Solution
- ☐ Injectable Solution Concentrate
- ☐ Injectable Suspension
- ☐ Lyophilized Powder for In Vitro Test
- ☐ Lyophilized Powder for Injectable Solution
- ☐ Lyophilized Powder for Injectable Suspension
- ☐ Lyophilized Powder for Scarification
- ☐ Lyophilized Powder to be suspended for Instillation
- ☐ Nasal Spray Suspension
- ☐ Powder for Reconstitution
- ☐ Solution for In Vitro Test
- ☐ Suspension for In Vitro Test
- ☐ Spray
- ☐ Tablet
- ☐ Powder for Injectable Solution
- ☐ Powder and Solvent for Suspension for Injection
- ☐ Repository Injection
- ☐ Other _____

### Potency Units

| | | | | |
|---|---|---|---|---|
| ☐ AU/.5mL | ☐ mg/.8 mL | ☐ dil. | ☐ mg/vial | ☐ ug/.4mL |
| ☐ AU/mL | ☐ other | ☐ g | ☐ Percent | ☐ ug/.5mL |
| ☐ BAU/mL | ☐ TCID | ☐ g/tube | ☐ u/.5mL | ☐ ug/.6mL |
| ☐ IU/.1 mL | ☐ TU/mL | ☐ mL | ☐ u/2mL | ☐ ug/g |
| ☐ IU/mL | ☐ U/.75mL | ☐ mg | ☐ u/mL | ☐ ug/mL |
| ☐ IU/vial | ☐ cell/mL | ☐ mg/0.5 mL | ☐ u/tube | ☐ ug/vial |
| ☐ Lf/.5mL | ☐ cfu/mL | ☐ mg/2 mL | ☐ u/vial | |
| ☐ MIU/mL | ☐ cfu/tab | ☐ mg/5 mL | ☐ ug | |
| ☐ MIU/vial | ☐ conc. | ☒ mg/mL | ☐ ug/.3mL | |

### Route of Administration

- ☐ Dental
- ☐ Implantation
- ☐ Inhalation
- ☐ Intracoronary
- ☐ Intradermal
- ☐ Intralesional
- ☐ Intralymphatic
- ☐ Intramuscular
- ☐ Intranasal
- ☐ Intraperitoneal
- ☐ Intrathecal
- ☐ Intratracheal
- ☐ Intravenous
- ☐ Intravesical
- ☐ Nasal Spray
- ☒ Other intravitreal
- ☐ Needle Free Injection
- ☐ Oral
- ☐ Percutaneous
- ☐ Prick Test
- ☐ Scratch Test
- ☐ Spinal
- ☐ Subcutaneous

# *Product Information Sheet - Components*

STN: 125156 1 0 Reg. Coordinator: Lori Gorski

Name polysorbate 20

**Component Type**

☒ Formulation ☐ Product ☐ In Process Ingredient ☐ Kit Component

**Ingredient Role -- (Pick one when Component Type "Formulation" is used)**

☐ Active ☐ Additive ☐ Diluent ☐ Preservative

Source _____ Subsource _____

Name _____

**Component Type**

☐ Formulation ☐ Product ☐ In Process Ingredient ☐ Kit Component

**Ingredient Role -- (Pick one when Component Type "Formulation" is used)**

☐ Active ☐ Additive ☐ Diluent ☐ Preservative ☐ Stabilizer

Source _____ Subsource _____

Name _____

**Component Type**

☐ Formulation ☐ Product ☐ In Process Ingredient ☐ Kit Component

**Ingredient Role -- (Pick one when Component Type "Formulation" is used)**

☐ Active ☐ Additive ☐ Diluent ☐ Preservative ☐ Stabilizer

Source _____ Subsource _____