CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

BLA 103792/5275

Trade Name: Herceptin

Generic Name: trastuzumab

Sponsor: Genentech, Inc.

Approval Date: February 23, 2012

Indications: For adjuvant treatment of HER2 over-expressing node-positive or high-risk node-negative breast cancer

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

BLA 103792/5275

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

BLA 103792/5275

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

SUPPLEMENT BLA APPROVAL

Our STN: BL 103792/5275

February 23, 2012

Genentech, Incorporated
Attention: Mary B. Sliwkowski, Ph.D.
Vice President, Pharma Technical Regulatory
1 DNA Way
South San Francisco, CA 94080-4990

Dear Dr. Sliwkowski:

Your request to supplement your biologics license application for Herceptin® (trastuzumab), to allow for the manufacture of trastuzumab drug substance (b) (4) at the Roche Diagnostics GmbH, Biologics IV facility in Penzberg, Germany, has been approved.

This information will be included in your biologics license application file.

Sincerely,

Kathleen A. Clouse, Ph.D.
Director
Division of Monoclonal Antibodies
Office of Biotechnology Products
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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/s/

KATHLEEN A CLOUSE STREBEL
02/23/2012

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

BLA 103792/5275

CHEMISTRY REVIEW(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Center for Drug Evaluation and Research - Food & Drug Administration
Laboratory of Molecular Oncology, Division of Monoclonal Antibodies – HFD-123
Office of Biotechnology Products/ Office of Pharmaceutical Sciences
NIH Campus, Bldg. 29B, Rm. 4NN20, 29 Lincoln Drive MSC 4555
Bethesda, MD 20892-4555

Subject: **STN 103792/5275, PRODUCT QUALITY REVIEW**

Date: February 22, 2012

From: Wendy C. Weinberg, HFD-123

Through: Patrick Swann, Deputy Director, DMA

To: File STN 103792 (file 1048)
cc: Andrew Shiber, Regulatory Project Manager, OPS/OBP

Product: Trastuzumab

Submission type: Prior Approval Supplement

Purpose of submission: To support the licensure of the Biologics IV facility in Penzberg, Germany as an additional manufacturing facility for Herceptin (trastuzumab) (b) (4) drug substance (DS), as well as additional testing sites for drug substance release and stability testing, and for mycoplasma and viral testing.

Date of Submission: October 21, 2011/received October 24, 2011

Action Date: February 23, 2012

Sponsor: Genentech, Inc.
Contact: Jenifer Lundberg (650) 225-3106

EDR location: (sequence 47)
http://cberedrweb.fda.gov:8080/esp/cberedr.jsp?folderObjId=0bbcaea680f1a91f

Recommendation: ***Approval. Based on the information provided, the manufacturing of Trastuzumab drug substance*** (b) (4) ***process at the Roche Diagnostics GmbH, Biologics IV facility in Penzberg, Germany is adequately controlled and Trastuzumab drug substance manufactured at this site is deemed comparable to licensed trastuzumab*** (b) (4)**.**

Background: Manufacture of Herceptin was initially licensed [redacted] in South San Francisco in September, 1998. This process was transferred to Vacaville in April, 2000. The [redacted] was approved in Vacaville in August 2004, [redacted] in September 2006 [redacted] and at Roche Singapore (RSTO) in September 2011. Manufacture of Herceptin [redacted] in Penzberg was approved by the EU in October 2010.

Summary/contents of submission:
This submission is to support the approval of the following:
- Roche Diagnostics GmbH, Penzberg, Germany, as an additional facility for the manufacture, release testing and stability testing of trastuzumab DS
- Roche Diagnostics GmbH, Mannheim, Germany, as an additional facility for potency assay release testing of trastuzumab DS
- Roche Diagnostics Quality Control Mycoplasma lab, GmbH, Penzberg, Germany, for mycoplasma testing
- [redacted] for virus testing

Note: The submission is in eCTD format and this review parallels the submission structure. Reviewer's comments are indicated with bolded, italicized font. All figures and tables shown were excerpted from the submission, unless otherwise noted.

The following components addressing comparability are included in the submission:

3.2.S.2.2	Description of processes/process controls/comparison of processes between facilities
3.2.S.2.3	Control of materials
3.2.S.2.4	Control of critical steps and intermediates
3.2.S.2.5	Process validation/evaluation
3.2.S.2.6	Manufacturing process development
3.2.S.3	Characterization, including comparability analysis
3.2.S.4	Control of DS, includes specifications, validation of analytical procedures, method transfers, batch analyses
3.2.S.7	Stability studies and commitments
3.2.A	Facilities and equipment, viral safety clearance studies
3.2.R	batch records

1.4.4: Cross Reference to Other Applications

The following previous submissions are referenced in the supplement:

- STN: BL 103792 (98-0369), Original Herceptin BLA, Approved 25 September 1998
- STN: BL 103792 (99-1479), Herceptin [redacted] at Vacaville, Approved 20 April 2000
- STN: BL 103792/5012, Approved 2 August 2002

- STN: BL 103792/5073, Herceptin [redacted] at Vacaville, Approved 5 April 2004
- STN: BL 103792/5118, Approved 1 September 2005
- STN: BL 103792/5131, Approved 15 December 2005
- STN: BL 103792/5154, Herceptin [redacted], Approved 1 September 2006
- STN: BL 103792/5258, [redacted] Approved 09 December 2010
- STN: BL 103792/5268, Herceptin [redacted] at Roche Singapore Technical Operations B10, Approved 12 September 2011

1.12.14: Environmental Analysis

Genentech requests a categorical exclusion under 21 CFR 25.31(c). ***This is deemed appropriate.***

3.2.S: Drug Substance

3.2.S.2.1: Manufacturing

Current facilities approved under STN 103792:

Trastuzumab drug substance manufacture, release testing, and stability testing:
Genentech South San Francisco (SSF)
Genentech Vacaville
Roche Singapore (RSTO)

Herceptin drug product (DP) manufacture:
Genentech SSF
[redacted]

Release testing of Herceptin DP:
Genentech SSF
Genentech Vacaville
[redacted]

Herceptin DP stability testing:
Genentech, SSF
Genentech, Vacaville

Herceptin DP final vial labeling and packaging:
[redacted]

Additional testing sites: virus and mycoplasma testing:
Genentech, Oceanside, CA
Roche Singapore (RSTO)

(b) (4)

Following this page, 40 Pages Withheld in Full as (b)(4)

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

/s/

WENDY C WEINBERG
02/22/2012

PATRICK G SWANN
02/23/2012

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

BLA 103792/5275

MICROBIOLOGY REVIEW

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Drug Evaluation and Research
WO Bldg 51
10903 New Hampshire Ave.
Silver Spring, MD 20993

Date: 21 February, 2012

To: Administrative File, STN 103792/5275

From: Reyes Candau-Chacon, PhD. Reviewer, OC/OMPQ/DGMPA/BMAB

Through: Patricia Hughes, Ph.D., Team Leader, OC/ OMPQ/DGMPA/BMAB

Subject: Review of Prior-approval Supplement (PAS) to support the Biologics IV facility in Penzberg (Germany) as an additional drug-substance manufacturing facility.

US License: 1048

Applicant: Genentech, Inc.

Facilities: Roche Diagnostics GmbH, Pharma Biotech Penzberg, Nonnenwald 2, D-82377 Penzberg, Germany (FEI 3002806560)

(b) (4)

Product: Herceptin® (trastuzumab)

Dosage: Lyophilized powder for reconstitution to be delivered as intravenous (IV) infusion in 20 mL glass vials containing 400 mg of trastuzumab

Indication: For the adjuvant treatment of HER2 over-expressing, node-positive or high-risk node-negative, breast cancer

Due date: 23 February 2012

Recommendation for Approvability: PAS 103792/5275 is recommended for approval from a microbial control and microbiology product quality perspective.

Following communication with the agency, the sponsor agreed upon the following post-approval commitments, which should be communicated to the sponsor:

1. Implement (b) (4) sampling for bioburden testing at the Vacaville and Singapore facilities and submit these changes to the Agency per CFR 601.12 by Q4 2012;
2. Implement (b) (4) sample volume for bioburden testing at the Penzberg facility by Q3 2012 upon completion of the method validation;
3. Perform (b) (4) for bioburden and endotoxin for (b) (4) at the Penzberg site and submit the results to the Agency in a CBE-0 by Q4 2012. (b) (4) will be performed for (b) (4) for Penzberg production lines (b) (4);

4. Perform a risk-assessment and risk-mitigation study regarding potential viral contamination in [redacted] (b) (4) and submit the results to the Agency in a CBE-0 by Q4 2012.

Review Summary

Genentech has submitted this Prior-approval Supplement in support of the new Biologics IV facility in Penzberg (Germany) as an additional manufacturing site for trastuzumab drug substance manufacture.

The PAS was submitted in eCTD format on 24-October-2011 under sequence #0047 and it include documents under Modules 1, 2, and 3. Module 2 contains a Quality Overall Summary, and Module 3 contains sections describing the manufacturing and control of drug substance (manufacture, characterization, control of drug substance, and stability), appendices describing the facilities, equipment and adventitious agents safety evaluation, and batch records. A teleconference was held between the Agency and Genentech on 20-Dec-2011, and two e-mails were sent on 24-Jan-202, and 14-Feb-2012. Genentech filed amendments #0053 on 23-Dec-2011, #0055 on 3-Feb-2012, and #0056 on 21-Feb-2012 to address questions sent by the Agency.

Review Narrative

3.2.S DRUG SUBSTANCE

3.2.S.1 General Information

[redacted] (b) (4) . Trastuzumab is indicated as part of a treatment regimen containing doxorubicin, cyclophosphamide, and docetaxel or docetaxel and carboplatin, for the adjuvant treatment of HER2 over-expressing, node-positive or high-risk node-negative, breast cancer.

3.2.S.2.1 Manufacturer(s)

Roche/Genentech is responsible for the manufacture, testing, and release of Herceptin® (trastuzumab) Drug Substance (Bulk for Storage) and Drug Product.

The following facilities are approved for the manufacture, release testing, and stability testing of trastuzumab Drug Substance:

- Genentech
  1 DNA Way, South San Francisco, CA 94080-4990. FEI No. 2917923
- Genentech
  1000 New Horizons Way, Vacaville, CA 95688-9431. FEI No. 3002902534
- Roche Singapore Technical Operations Pte. Ltd.
  10 Tuas Bay Link, Singapore 637394. FEI No. 3007164129

The following facility is proposed as an additional facility for the manufacture, release testing, and stability testing of trastuzumab Drug Substance:

- Roche Diagnostics GmbH Pharma Biotech Penzberg
  Nonnenwald 2, D-82377 Penzberg, Germany. FEI No. 3002806560

In addition to testing in South San Francisco, virus and mycoplasma testing may occur at the Quality Control Virus and Mycoplasma lab at the following locations:

- Genentech
  One Antibody Way, Oceanside, CA 92056-5802. FEI No. 3006129086
- Roche Singapore Technical Operations Pte. Ltd.
  10 Science Park Road, Singapore 637394. FEI No. 3007164129

The following Quality Control Mycoplasma lab is proposed as an additional lab for mycoplasma testing:

- Roche Diagnostics GmbH Pharma Biotech Penzberg
  Nonnenwald 2, D-82377 Penzberg, Germany. FEI No. 3002806560

The following Quality Control Virus lab is proposed as an additional lab for virus testing:

- (b) (4)

Reviewer comments:
Refer to the cGMP status section of this review for the compliance status of the manufacturing and testing sites.

3.2.S.2.2 (b) (4)

Following this page, 28 Pages Withheld in Full as (b)(4)

Environmental Assessment

The supplement does not involve the introduction of a new unlicensed molecular entity or an increase in the use of the active moiety; therefore, environmental assessment information is not required.

cGMP Status

The Manufacturing Assessment and Pre-Approval Compliance Branch has completed its review and evaluation of the submitted site. The sites have an acceptable cGMP compliance status. The status for the site as of 2/21/2012 is the following:

Establishment	FEI	Inspection Date	Classification	Profile
Roche Diagnostics GmbH, Nonnenwald 2, D-82377 Penzberg, Germany	3002806560	From 9-Jan-12 to 17-Jan-12	VAI	Acceptable
(b) (4)				

Conclusion

I. The Prior-approval Supplement was reviewed from a microbial control and microbiology product quality perspective and is recommended for approval.

II. The supplement should be reviewed by an OBP/DMA reviewer, specifically concerning stability.

III. The Roche Diagnostics GmbH, Penzberg, Germany was inspected by a team of investigators (Bo Chi, Ph.D., Reyes Candau-Chacon, Ph.D., Carla SR. Lankford, Ph.D. and Linan Ha, Ph.D.) from January 09, 2012 to January 17, 2012.

Cc: OC/ OMPQ/DGMPA/WO Bldg 51, Candau-Chacon
OC/ OMPQ/DGMPA/WO Bldg 51, Hughes
OPS/OBP/WO Bldg 21, Shiber

FDA Information Request for STN 103792/5275

1. (b) (4)
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Candauchacon, Maria

From: Candauchacon, Maria
Sent: Tuesday, January 24, 2012 4:16 PM
To: 'Jenifer Lundberg'
Cc: Hughes, Patricia
Subject: STN 103792/5275 Trastuzumab

Hi Jennifer,
During the inspection at Penzberg I discussed with (b) (4) for microbial quality. We discussed the following two approaches: (b) (4) and establish bioburden and endotoxin limits or amend the submission and limit the (b) (4). Please clarify which approach Roche intends to follow. A post marketing commitment before the action date will be necessary if Roche intends to (b) (4)

Also, please amend the submission to indicate that (b) (4) during Trastuzumab manufacturing.

Thank you,

Reyes Candau-Chacon, PhD.
Biologist
Biotech Manufacturing Assessment Branch
Division of Good Manufacturing Practice Assessment
Office of Manufacturing and Product Quality
Office of Compliance
Center for Drug Evaluation and Research

Candauchacon, Maria

From: Candauchacon, Maria
Sent: Tuesday, February 14, 2012 3:29 PM
To: 'Jenifer Lundberg
Cc: Hughes, Patricia
Subject: STN103792-5275 trastuzumab

Jennifer,
We are requesting the following items regarding STN 103792/5275 for Trastuzumab:

- The amendment #0055 indicates Roche's commitment to perform (b) (4) validation for bioburden and endotoxin for (b) (4) at the Penzberg site. Please, indicate when the data will be submitted to the Agency.
- In the information request sent by the Agency on December 13th, we asked to (b) (4) bioburden sample volumes to (b) (4) Please, commit to (b) (4) bioburden sample volumes to (b) (4) and indicate when the (b) (4) sampling volume will be implemented.
- Submit to the Agency the results for the risk assessment and risk mitigation regarding potential viral contamination in (b) (4)

Thank you,

Reyes Candau-Chacon, PhD.
Biologist
Biotech Manufacturing Assessment Branch
Division of Good Manufacturing Practice Assessment
Office of Manufacturing and Product Quality
Office of Compliance
Center for Drug Evaluation and Research

Candauchacon, Maria

From: Ramanadham, Mahesh
Sent: Wednesday, February 22, 2012 11:14 AM
To: Candauchacon, Maria
Cc: CDER-TB-EER
Subject: RE: STN 103792/5275 Trastuzumab

Dear Reyes, there are no pending or ongoing compliance actions that prevent approval of this supplement.

Roche Diagnostics GmbH,
Nonnenwald 2, D-82377 Penzberg, Germany
3002806560
Drug Substance Manufacturing, Control Testing

Inspected by BMAB from 9-Jan-12 to 17-Jan-12. This was a pre-licensing inspection to support the use of this facility as an additional DS manufacturer. This site has been classified VAI following DIDQ review of the 483 response and response to an RAI letter. The TRP profile will be entered as acceptable.

(b) (4)

(b) (4)

From: Candauchacon, Maria
Sent: Tuesday, February 21, 2012 10:20 AM
To: CDER-TB-EER
Subject: STN 103792/5275 Trastuzumab

Hello,
Could you send me a compliance check for the following facilities? The facility was inspected in January and it was just approved by Mary Farbman. Please, note that the PDUFA date is tomorrow. Could you also update the CC for the other facilities?
Thanks,
Reyes

Subject: Review of Prior-approval Supplement (PAS) to support the Biologics IV facility in Penzberg (Germany) as an additional drug-substance manufacturing facility.

US License: 1048

Applicant: Genentech, Inc.

Facilities: Roche Diagnostics GmbH, Pharma Biotech Penzberg, Nonnenwald 2, D-82377 Penzberg, Germany
(FEI 3002806560)

Product: Herceptin® (trastuzumab)

Dosage: Lyophilized powder for reconstitution to be delivered as intravenous (IV) infusion in 20 mL glass vials containing 400 mg of trastuzumab

Indication: For the adjuvant treatment of HER2 over-expressing, node-positive or high-risk node-negative, breast cancer

1

Due date: 23 February 2012

Establishment	FEI	Inspection Date	Classification	Profile
Roche Diagnostics GmbH, Nonnenwald 2, D-82377 Penzberg, Germany	3002806560	From 9-Jan-12 to 17-Jan-12	VAI	Acceptable
				(b) (4)

2

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/s/

REYES CANDAU-CHACON
02/22/2012

PATRICIA F HUGHES TROOST
02/22/2012

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

BLA 103792/5275

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

LICENSING ACTION RECOMMENDATION

Applicant: Genentech Inc. **STN:** 103792/5275

Product:

Herceptin® (trastuzumab)

Indication / manufacturer's change:

To allow for the manufacture of trastuzumab drug substance (b) (4) at the Roche Diagnostics GmbH, Biologics IV facility in Penzberg, Germany.

■ Approval:
- ■ Summary Basis For Approval (SBA) included
- ☐ Memo of SBA equivalent reviews included
- ☐ Refusal to File: Memo included
- ☐ Denial of application / supplement: Memo included

RECOMMENDATION BASIS

■ Review of Documents listed on Licensed Action Recommendation Report

☐ Inspection of establishment ☐ Inspection report included

☐ BiMo inspections completed ☐ 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 – PRODUCT RELEASE BRANCH

■ CBER Lot release not required

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

☐ Lot no.(s) for release _____

Director, Product Release Branch _____

CLEARANCE – REVIEW

Review Committee Chairperson: Wendy Weinberg Date: _____

Product Office's Responsible Division Director(s)*:

Kathleen Clouse Date: _____

_____ Date: _____

DMPQ Division Director* : _____ Date: _____

* If Product Office or DMPQ Review is conducted

CLEARANCE – APPLICATION DIVISION

■ Compliance status checked ■ Acceptable ☐ Hold Date: 2/22/12

☐ Cleared from Hold Date: _____

☐ Compliance status check Not Required

Regulatory Project Manager (RPM) Andrew Shiber Date: _____

Responsible Division Director _____ Date: _____
(where product is submitted, e.g., application division or DMPQ)

Form DCC-201 (05/2003)

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/s/

ANDREW J SHIBER
02/23/2012
LARM

WENDY C WEINBERG
02/23/2012

KATHLEEN A CLOUSE STREBEL
02/23/2012

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Science
Office of Biotechnology Products

FACSIMILE TRANSMITTAL SHEET

DATE: December 14, 2011

To: Dr. Sliwkowski	**From:** CDR Andrew Shiber, Pharm.D.
Company: Genentech, Inc.	CDER/OPS/OBP
Fax number: 650-467-3198	**Fax number:** (301) 796-9743
Phone number: 650-225-2880	**Phone number:** (301) 796-4798

Subject: STN 103792/5275

Total no. of pages including cover: 3

Comments: Please find following an information request for your PAS for Herceptin® (trastuzumab). Please contact me if you have any questions and let me know when you are sending in an amendment.

Document to be mailed: ☐ YES X NO

Information Request for STN 103792/5275

We are currently reviewing your PAS submission of 24-Oct-11. The following IR items require appropriate and timely reply in order to complete our assessment of this supplement. Please submit your response prior to COB 12/28/2011.

Comments for the sponsor:

(b) (4)

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(b) (4)

11.

12.

If you have any questions, please contact me.

Sincerely,

CDR Andrew Shiber, Pharm.D.
Office of Biotechnology Products
Office of Pharmaceutical Science
Center for Drug Evaluation and Research
Andrew.Shiber@fda.hhs.gov

PRODUCT QUALITY (Biotechnology)
FILING REVIEW FOR BLA/NDA Supplements (OBP & DMPQ)

BLA/NDA Number:	Applicant:	Stamp Date:
103792/5275	Genentech, Inc.	24-Oct-11
Established/Proper Name:	**BLA/NDA Type:**	
Herceptin®/trastuzumab	BLA	

Brief description of the change:	To support the licensure of the Biologics IV facility in Penzberg, Germany as an additional manufacturing facility for Herceptin (trastuzumab) (b) (4) drug substance.
Reviewer:	Maria Candau-Chacon
Office/Division:	BMAB/DGMPA/OMPQ

On **initial** overview of the BLA/NDA **supplement** for filing:

The following was submitted in support of the change (check all that apply):

X	A detailed description of the proposed change
X	Identification of the product(s) involved
X	A description of the manufacturing site(s) or area(s) affected
X	A description of the methods used and studies performed to evaluate the effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product
X	The data derived from such studies
X	Relevant validation protocols and data
X	A reference list of relevant standard operating procedures (SOP's)

The following deficiencies were identified (identify those that are potential filing issues):

IS THE PRODUCT QUALITY SECTION OF THE SUPPLEMENT FILEABLE? **Yes** ~~**No**~~

If the supplement is not file able from the product quality perspective, state the reasons and provide comments to be sent to the Applicant.

Please identify and list any potential review issues to be forwarded to the Applicant for the 74-day letter.

Reyes Candau-Chacon	Nov-29-2011
Product Quality Reviewer	Date
Patricia Hughes	Nov-29-2011
Branch Chief/Team Leader/Supervisor	Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Our STN: 103792/5275

PRIOR APPROVAL SUPPLEMENT ACKNOWLEDGEMENT

Genentech, Incorporated
Attention: Mary B. Sliwkowski, Ph.D.
Vice President, Pharma Technical Regulatory
1 DNA Way
South San Francisco, CA 94080-4990

October 27, 2011

Dear Dr. Sliwkowski,

We have received your supplement to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for the following biological product:

STN BL:	103792/5275
Biological Product:	Herceptin® (trastuzumab)
Reason for the submission:	To support the licensure of the Biologics IV facility in Penzberg, Germany as an additional manufacturing facility for Herceptin (trastuzumab) (b) (4) drug substance.
Date of Supplement:	21-Oct-11
Date of Receipt:	24-Oct-11
Action Due Date:	**February 23, 2012**
US License Number:	1048

Unless we notify you within 60 days of the receipt date that the supplement is not sufficiently complete to permit substantive review, this supplement will be considered filed.

All future correspondence or supportive data relating to this supplemental application should bear the above STN.

This acknowledgment does not mean that this supplement has been approved nor does it represent any evaluation of the adequacy of the data submitted. Following a review of this submission, we shall advise you in writing as to what action has been taken and request additional information if needed.

If you have any questions, please contact me at (301) 796-4798

Sincerely,

CDR Andrew Shiber, Pharm.D.
Office of Biotechnology Products
Office of Pharmaceutical Science
Center for Drug Evaluation and Research
Andrew.Shiber@fda.hhs.gov

Shiber, Andrew J

From: Hughes, Patricia
Sent: Tuesday, October 25, 2011 11:21 AM
To: Shiber, Andrew J; Swann, Patrick G.; Weinberg, Wendy; Candauchacon, Maria
Subject: RE: (RAR) PAS Genentech 103792/5275

Please assign to Reyes Candau-Chacon. This may require an inspection of the Penzberg site.

Patricia

From: Shiber, Andrew J
Sent: Tuesday, October 25, 2011 9:05 AM
To: Swann, Patrick G.; Hughes, Patricia; Weinberg, Wendy
Subject: (RAR) PAS Genentech 103792/5275

Good Day Review Team,

OBP has received a PAS supplement from:

Manufacturer: Genentech, Inc.
Date of Submission: 21-Oct-11
CBER Receipt Date: 24-Oct-11
DCC Login ID 60015790
Product: trastuzumab
STN 103792/5275
Action Date: **February 23, 2012**
Description: To support the licensure of the Biologics IV facility in Penzberg, Germany as an additional manufacturing facility for Herceptin (trastuzumab) (b) (4) drug substance.

Patrick,
Wendy Weinberg will be the DMA reviewer assigned.

Patricia,
Please assign a BMT reviewer. The link to the supplement has been provided below.

http://cberedrweb.fda.gov:8080/esp/cberedr.jsp?folderObjId=0bbcaea680f1a91f

Under sequence: 47

Thank you for your help.

Andrew