

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Corixa Corporation

License No.: 25-19852-01

Docket No.: 030-19324

Mail Control No.: 471012

Type of Action: Amend

Date of Requested Action: 06-08-06

Reviewer Assigned: TORRES

ARM reviewer(s): Torres

Response	Deficiencies Noted During Acceptance Review
	1. [] Open ended possession limits. Submit inventory. Limit possession. [] Inform licensee that we are limiting possession limits. [] Ask the licensee if they have any type-amount of EPAct Material.
<u>7/5/06</u>	2. Submit Appendix F.
	3.

Reviewer's Initials: RITC

Date: 7/5/06

- ☐ Yes ☐ No Request for unrestricted use for Group 2 or higher category should be transferred by memo to FCDB within 10 days of receipt.
- ☐ Yes ☐ No Decommissioning notification should be completed within 30 days.
- ☐ Yes ☐ No Termination request < 90 days from date of expiration
- ☐ Yes ☐ No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
- ☐ Yes ☐ No TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: _____

Date: _____

SUNSI Screening according to RIS 2005-31

☐ Yes ☒ No **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

- ☒ RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- ☒ Exact location of RAM (whether = or > than Category 3 or not)
- ☒ Design of structure and/or equipment (site specific)
- ☒ Information on nearby facilities
- ☒ Detailed design drawings and/or performance information
- ☒ Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- ☒ RAM quantities and inventory
- ☒ Manufacturer's name and model number of sealed sources & devices
- ☒ Site drawings with exact location of RAM, description of facility
- ☒ RAM security program information (locks, alarms, etc.)
- ☒ Emergency Plan specifics (routes to/from RAM, response to security events)
- ☒ Vulnerability/security assessment/accident-safety analysis/risk assess
- ☒ Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: RITC

Date: 6/21/06



GlaxoSmithKline

**GlaxoSmithKline
Biologicals North America**
553 Old Corvallis Road
Hamilton, MT 59840
USA

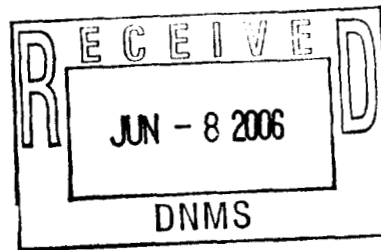
www.gsk-bio.com

June 8, 2006

Colleen Murnahan
U.S. NRC Region IV
Texas Health Resources Tower
611 Ryan Plaza, Suite 400
Arlington, TX 76011-4005

RE: NRC License No. 25-19852-01

Dear Colleen Murnahan,



(This letter is to amend the GlaxoSmithKline Biologicals- Hamilton (formerly Corixa Corporation) NRC radioactive materials license, No. 25-19852-01.)

GSK Bio- Hamilton wishes to formerly apprise the NRC of management's intent to decommission and demolish the licensed outdoor facility listed as Building 7. The licensed room located in Building 7 was previously used for storage and decay of radioactive isotopes. No materials are currently present in this room or in Building 7. Pacific Health Physics performed decommissioning, under the supervision of Michael Simmons and GSK Bio- Hamilton personnel. All appropriate NRC, federal, state and local regulations and guidelines will be followed. Please find the attached site map and decommission report for your review.

We are currently undergoing a facility expansion. The demolition of Building 7 is critical to the established project timeline. If possible, an expedited assessment of this amendment would be greatly appreciated.

If you have any questions, please feel free to contact me directly at 406-375-2129 or brian.j.poletti@gskbio.com.

Sincerely,

Brian Poletti
EH&S Associate/RSO
GlaxoSmithKline Biologicals- Hamilton

471012

From: <brian.j.poletti@gskbio.com>
To: "Roberto Torres" <RJT@nrc.gov>
Date: 07/05/2006 11:22:28 AM
Subject: Re: Fwd: Re: Amendment request

Mr. Torres,

Please find the attached pdf file. Hopefully, I filled in the required information appropriately.

Brian

"Roberto Torres" <RJT@nrc.gov>
05-Jul-2006 09:23

To
<brian.j.poletti@gskbio.com>
cc

Subject
Fwd: Re: Amendment request

Mr. Poletti:

Please let me know when can I expect to receive the attached form. If the formal name change is going to take longer than a month then I will make a note in our files, will wait until you formally notify us and will not track this as an immediate licensing action.

The evaluation by NRC of the decommissioning of building 7 will proceed as a separate licensing action and will not be affected by the proposed name change.

Roberto J. Torres
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region IV
Division of Nuclear Materials Safety
Nuclear Materials Licensing Branch
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011
Telephone 817-860-8189
Facsimile 817-860-8188
rjt@nrc.gov

>>> <brian.j.poletti@gskbio.com> 06/21/2006 12:39 PM >>>

Mr. Torres,

Thank you for your acknowledgement. We have not formally changed the name

on the license, because we are still technically "Corixa" as well, a subsidiary of GlaxoSmithKline Biologicals. I will complete and return the form.

Regards,
Brian

Brian Poletti
EH&S Associate/RSO
GlaxoSmithKline Biologicals
553 Old Corvallis Rd.
Hamilton, MT 59840
(406)375-2129

"Roberto Torres" <RJT@nrc.gov>
21-Jun-2006 11:07

To
<brian.j.poletti@gskbio.com>
cc
"Blair Spitzberg" <DBS@nrc.gov>, "Jack Whitten" <JEW1@nrc.gov>
Subject
Amendment request

Mr. Poletti:

This email acknowledges receipt of your expedited amendment request to decommission building 7. We will forward your request to our Decommissioning Branch for them to review the decommissioning report to determine releasability for unrestricted use.

On a separate matter, 10 CFR 30.34(b) states that "no license issued or granted pursuant to the regulations...nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall...find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing." I noted a change of company name in your letterhead. Please fill out and have the attached Change of Ownership form

signed to be in compliance with this regulatory requirement. Call me if you have any questions on how to fill the form.

Roberto J. Torres
Acting Chief

U.S. Nuclear Regulatory Commission, Region IV
Division of Nuclear Materials Safety
Nuclear Materials Licensing Branch
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011
Telephone 817-860-8189
Facsimile 817-860-8188
rjt@nrc.gov

[attachment "Appendix F Change of Ownership.pdf" deleted by Brian J Poletti/PharmUS/GSK]

The information contained in this message is confidential and is intended for the addressee(s) only. This information may also be legally privileged. If you have received this message in error or there are any problems please notify the originator immediately.

The unauthorized use, disclosure, copying or alteration of this message is strictly forbidden. GlaxoSmithKline Biologicals s.a. will not be liable for direct, special, indirect or consequential damages arising from alteration of the contents of this message by a third party or as a result of any virus being passed on.

[attachment "Appendix F Change of Ownership.pdf" deleted by Brian J Poletti/PharmUS/GSK]

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Information Required for Change of Control and/or Change of Ownership
(to include a name change)

Source: NUREG-1556, Volume 15

Please provide the following information concerning changes of control (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (i.e., transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.

A. Description of the transaction:

CASH FOR STOCK ACQUISITION

B. ☐ No name change

☒ New name of licensed organization: GLAXO SMITHKLINE BIOLOGICS - HAMILTON

C. ☒ No change in contact

☐ New contact: _____

☐ New telephone number: _____

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

A. ☒ No changes in personnel having control over licensed activities.

☐ Changes in personnel having control over licensed activities (e.g. officers of a corporation):

B. ☒ No changes in personnel named in the license.

☐ Changes in personnel named in the license (e.g. RSO, AUs) - include training, experience and responsibilities:

3. Describe, in detail, any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

☐ Organization:

☐ Equipment:

☐ Location:

☐ Procedures:

☐ Facility:

☒ Not applicable

471012

4. Describe the status of the surveillance program (i.e., surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

- A. Description of the status of all surveillance program:

THE STATUS OF OUR SURVEILLANCE PROGRAM IS CURRENT. OUR FACILITIES RADIATION PROGRAM WILL NOT BE AFFECTED BY THIS ACQUISITION,

- B. Surveillance Items & Records: calibrations, leak tests, surveys, inventories, and accountability requirements will be current at the time of transfer

☒ Yes ☐ No (explain)

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

Records transferred to:

☐ New licensee ☐ NRC for license termination ☒ Not applicable

6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

GLAXOSMITHKLINE BIOLOGICS - HAMILTON will abide by all constraints, conditions,
(transferee company)
requirements and commitments of CORIXA CORPORATION
(transferor company)

Signature/Title
Transferee Official

Signature/Title
Transferor Official

date

date

OR

- ☐ Description of proposed licensed program from transferee attached (with signature)

OR

☒ Not applicable (name change only)

Certifying Officer - Signature

Date

BRIAN POLETTI ENH'S ASSOCIATE/RSO
Certifying Officer - Typed name and title

Mail Envelope Properties (44ABE724.43A : 5 : 5178)

Subject: Re: Fwd: Re: Amendment request
Creation Date 07/05/2006 11:21:28 AM
From: <brian.j.poletti@gskbio.com>
Created By: brian.j.poletti@gskbio.com

Recipients

nrc.gov

ARL_PO.ARL_DO

RJT (Roberto Torres)

Post Office

ARL_PO.ARL_DO

Route

nrc.gov

Files	Size	Date & Time
MESSAGE	4190	07/05/2006 11:21:28 AM
TEXT.htm	5765	
Doc060705.pdf	106052	
Mime.822	156758	

Options

Expiration Date: None
Priority: Standard
ReplyRequested: No
Return Notification: None

Concealed Subject: No
Security: Standard

Junk Mail Handling Evaluation Results

Message is eligible for Junk Mail handling
This message was not classified as Junk Mail

Junk Mail settings when this message was delivered

Junk Mail handling disabled by User
Junk List is not enabled
Junk Mail using personal address books is not enabled
Block List is not enabled

From: <brian.j.poletti@gskbio.com>
To: "Roberto Torres" <RJT@nrc.gov>
Date: 06/21/2006 12:40:39 PM
Subject: Re: Amendment request

Mr. Torres,

Thank you for your acknowledgement. We have not formally changed the name on the license, because we are still technically "Corixa" as well, a subsidiary of GlaxoSmithKline Biologicals. I will complete and return the form.

Regards,
Brian

Brian Poletti
EH&S Associate/RSO
GlaxoSmithKline Biologicals
553 Old Corvallis Rd.
Hamilton, MT 59840
(406)375-2129

"Roberto Torres" <RJT@nrc.gov>
21-Jun-2006 11:07

To
<brian.j.poletti@gskbio.com>
cc
"Blair Spitzberg" <DBS@nrc.gov>, "Jack Whitten" <JEW1@nrc.gov>
Subject
Amendment request

Mr. Poletti:

This email acknowledges receipt of your expedited amendment request to decommission building 7. We will forward your request to our Decommissioning Branch for them to review the decommissioning report to determine releasability for unrestricted use.

On a separate matter, 10 CFR 30.34(b) states that "no license issued or granted pursuant to the regulations...nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall...find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing." I noted a change of company name in your letterhead. Please fill out and have the attached Change of Ownership form signed to be in compliance with this regulatory requirement. Call me if you have any questions on how to fill the form.

Roberto J. Torres
Acting Chief
U.S. Nuclear Regulatory Commission, Region IV
Division of Nuclear Materials Safety
Nuclear Materials Licensing Branch
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011
Telephone 817-860-8189
Facsimile 817-860-8188
rjt@nrc.gov

[attachment "Appendix F Change of Ownership.pdf" deleted by Brian J
Poletti/PharmUS/GSK]

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Mail Envelope Properties (44998482.5DF : 11 : 1503)

Subject: Re: Amendment request
Creation Date 06/21/2006 12:39:54 PM
From: <brian.j.poletti@gskbio.com>

Created By: brian.j.poletti@gskbio.com

Recipients

nrc.gov

ARL_PO.ARL_DO

RJT (Roberto Torres)

Post Office

ARL_PO.ARL_DO

Route

nrc.gov

Files	Size	Date & Time
MESSAGE	2475	06/21/2006 12:39:54 PM
TEXT.htm	3744	
Mime.822	7615	

Options

Expiration Date: None
Priority: Standard
ReplyRequested: No
Return Notification: None

Concealed Subject: No
Security: Standard

Junk Mail Handling Evaluation Results

Message is eligible for Junk Mail handling
This message was not classified as Junk Mail

Junk Mail settings when this message was delivered

Junk Mail handling disabled by User
Junk Mail handling disabled by Administrator
Junk List is not enabled
Junk Mail using personal address books is not enabled
Block List is not enabled

From: Roberto Torres
To: brian.j.poletti@gskbio.com
Date: 06/21/2006 12:07:27 PM
Subject: Amendment request

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611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011
Telephone 817-860-8189
Facsimile 817-860-8188
rjt@nrc.gov

CC: Blair Spitzberg; Jack Whitten

471012

Mail Envelope Properties (44997CCF.76A : 18 : 64234)

Subject: Amendment request
Creation Date 06/21/2006 12:07:27 PM
From: Roberto Torres

Created By: RJT@nrc.gov

Recipients	Action	Date & Time
gskbio.com brian.j.poletti (brian.j.poletti@gskbio.com)		
nrc.gov ARL_PO.ARL_DO PM DBS CC (Blair Spitzberg) JEW1 CC (Jack Whitten)	Delivered	06/21/2006 12:07:27

Post Office	Delivered	Route
ARL_PO.ARL_DO	Pending 06/21/2006 12:07:27 PM	gskbio.com nrc.gov

Files	Size	Date & Time
MESSAGE	1935	06/21/2006 12:07:27 PM
Appendix F Change of Ownership.pdf		145501 10/14/2005 4:09:36
PM		

Options

Auto Delete:	No
Expiration Date:	None
Notify Recipients:	Yes
Priority:	Standard
ReplyRequested:	No
Return Notification:	None

Concealed Subject:	No
Security:	Standard

To Be Delivered:	Immediate
Status Tracking:	Delivered & Opened

471012

Change of Control and/or Change of Ownership
(includes Change of Name)

10 CFR 30.34(b) states that "no license issued or granted pursuant to the regulations...nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall...find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing. Although not specifically addressed by 10 CFR 30.34, licensees undergoing a name change may also be affected by this regulation.

Control over licensed activities can be construed as the authority to decide when and how a license (licensed material and/or activities) will be used. A change of ownership may be an example of a change of control. The central issue is whether the authority over the license has changed. In all cases, determining whether a change of control has taken place or whether a change is in name only is the Commission's responsibility.

Licensees must notify the Commission when they are undergoing a possible change of control and/or a change of name. While this notification is not required within a certain time frame, NRC needs adequate time to review the submittal to ensure that the transfer is in accordance with the regulations.

In order to process your request for a change of control/ownership and/or a name change, the information on the following pages is required. Our fax number is (817) 860-8263 or (817) 860-8188. If you have any questions regarding our discussion or this fax, please contact me. When responding to this fax, please include the license, docket, and mail control numbers, located at the top of this page as well as the following pages. Thank you.

Information Required for Change of Control and/or Change of Ownership
(to include a name change)

Source: NUREG-1556, Volume 15

Please provide the following information concerning changes of control (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (i.e., transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.

A. Description of the transaction:

B. ☐ No name change

☐ New name of licensed organization: _____

C. ☐ No change in contact

☐ New contact: _____

☐ New telephone number: _____

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

A. ☐ No changes in personnel having control over licensed activities.

☐ Changes in personnel having control over licensed activities (e.g. officers of a corporation):

B. ☐ No changes in personnel named in the license.

☐ Changes in personnel named in the license (e.g. RSO, AUs) - include training, experience and responsibilities:

3. Describe, in detail, any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

☐ Organization:

☐ Equipment:

☐ Location:

☐ Procedures:

☐ Facility:

☐ Not applicable

4. Describe the status of the surveillance program (i.e., surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

A. Description of the status of all surveillance program:

B. Surveillance Items & Records: calibrations, leak tests, surveys, inventories, and accountability requirements will be current at the time of transfer

☐ Yes ☐ No (explain)

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

Records transferred to:

☐ New licensee ☐ NRC for license termination ☐ Not applicable

6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

_____ will abide by all constraints, conditions,
(transferee company)
requirements and commitments of _____
(transferor company)

Signature/Title
Transferee Official

Signature/Title
Transferor Official

date

date

OR

☐ Description of proposed licensed program from transferee attached (with signature)

OR

☐ Not applicable (name change only)

Certifying Officer - Signature

Date

Certifying Officer - Typed name and title

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)

INFORMATION FROM LTS

Program Code: 03620
Status Code: 0
Fee Category: 3M
Exp. Date: 20150630
Fee Comments:
Decom Fin Assur Regd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: CORIXA CORPORATION
Received Date: 20060608
Docket No: 30193324
Control No.: 471012
License No.: 25-19852-01
Action Type: Amendment

2. FEE ATTACHED

Amount:
Check No.:

3. COMMENTS

Signed
Date

Colleen M. Muehlen
06/27/06

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / __/)

1. Fee Category and Amount:

2. Correct Fee Paid. Application may be processed for:
Amendment
Renewal
License

3. OTHER

Signed
Date