

DATE: December 12, 2013

TO: Tania Steele

FROM: Eshetu Beshada, Ph.D., P.Eng.
Environmental Engineer
Mines and Wastewater Section
160 - 123 Main Street
Winnipeg, Mb R3C 1A5
Ph: (204) 945-7023

SUBJECT: **Pfizer Canada Inc. – Pharmaceutical Manufacturing – Information for Public Registries**

Tania,

Please find attached the TAC correspondence related to Pfizer Canada Inc – Pharmaceutical Manufacturing Facility file (5642.00) for distribution to the public registries. The documents included are:

1. Response to TAC Comments

- May 28, 2013 e-mail from Ian McGregor with attachment, 4 pages

2. TAC Comments

- May 23, 2013 e-mail from Adara Kaita, 1 page
- May 21, 2013 e-mail from Elise Watchorn, 1 page
- May 21, 2013 e-mail from Cheryl Kubish, 1 page
- May 20, 2013 e-mail from Jeff Long and Laureen Janusz, 1 page
- May 15, 2013 e-mail from James Stibbard, 1 page
- May 13, 2013 e-mail from Jason Kelly, 1 page
- May 9, 2013 e-mail from Sandra Allison, 2 page
- May 3, 2013 letter from Ryan Coulter, 1 page
- April 18, 2013 e-mail from Jonathan Wiens, 1 page

14 pages total

Thank you.

Eshetu Beshada, Ph.D., P.Eng.

Beshada, Eshetu (CWS)

From: Kaita, Adara (CWS) on behalf of +WPG1212 - Conservation_Circulars (CWS)
Sent: May-23-13 10:54 AM
To: Jackson, Adrian (CWS)
Subject: EA Proposal - Pfizer Pharmaceuticals - File: 5642.00

Hi Adrian,

The Sustainable Resource and Policy Management Branch and the Lands Branch have no concerns with the EA proposal.

Adara Kaita

Crown Land Programs and Policy Manager
Conservation and Water Stewardship
Box 25, 200 Saulteaux Crescent
Winnipeg, MB R3J 3W3
Cell: (204) 945-6301
F: (204) 948-2197

Beshada, Eshetu (CWS)

From: Watchorn, Elise (CWS)

Sent: May-21-13 4:08 PM

To: Jackson, Adrian (CWS)

Subject: FW: Request for review & comments - Pfizer Pharmaceuticals - Brandon File: 5642.00 - Closing date: May 21, 2013

Hello Adrian,

My section will have comments for this proposal, although I don't have them complete for you today. Would it be possible to request a copy of the proponent's emergency management and spill response plans? Most of my comments pertain to this area, so where their own protocols are sufficient, it would be helpful to couch licence terms in their words.

Also, who is the contact at Thompson Dorfman Sweatman to arrange to view the relevant proprietary information?

Thanks, and hope to have this to you asap!

Elise Watchorn, M.Sc.

Water Quality Specialist

Manitoba Conservation and Water Stewardship

Beshada, Eshetu (CWS)

From: Kubish, Cheryl (OFC)

Sent: May-21-13 10:25 AM

To: Jackson, Adrian (CWS)

Cc: Schafer, Dave (OFC)

Subject: FW: Request for review & comments - Pfizer Pharmaceuticals - Brandon File: 5642.00 - Closing date: May 21, 2013

The following response is forwarded on behalf of David Schafer, Fire Commissioner.

The Office of the Fire Commissioner has no concerns with the proposed application for an environmental license for this facility.

We recognize that this facility has been in operation since 1966, and that PGS Brandon maintains active membership in the Brandon Emergency Support Team (BEST) and works cooperatively with the City and other industrial partners through this organization to develop community preparedness action plans for potential emergencies and spills.

Cheryl Kubish
Administrative Assistant
Office of the Fire Commissioner
508-401 York Avenue
Winnipeg
Phone: 945-3328
Fax: 948-2089

E-Mail address: Cheryl.Kubish@gov.mb.ca

Beshada, Eshetu (CWS)

From: Long, Jeff (CWS)
Sent: May-20-13 10:04 PM
To: Janusz, Laureen R (CWS); Jackson, Adrian (CWS)
Cc: Bruederlin, Bruno (CWS)
Subject: RE: EAP 5642 Pfizer Pharmaceuticals - Brandon due May 21 2013

Hi All,

I am not sure that any wastewater treatment (primary, secondary or tertiary) removes hormones. I wonder, should we be concerned about estrogen loading? Are we seeing an imbalance in the sex ratio of the fish in the Assiniboine?

This is not an issue that we can answer, but we should have it on our radar. I expect that WQ continues to monitor for hormone levels in the water, but regardless, it remains a conceptual concern in the "environment literature"

Jeff Long, Ph.D. |Manager - Fisheries Science and Fish Culture |

MB Fisheries Branch - Conservation and Water Stewardship, |200 Saulteaux Cres.
Winnipeg, Manitoba |R3J 3W3 email: jeff.long@gov.mb.ca |Tel. 204.945.7792
Cell. 204.232.6870 |Fax. 204.948.2308

From: Janusz, Laureen R (CWS)
Sent: May-19-13 1:51 PM
To: Jackson, Adrian (CWS)
Cc: Bruederlin, Bruno (CWS); Long, Jeff (CWS)
Subject: EAP 5642 Pfizer Pharmaceuticals - Brandon due May 21 2013

Hi Adrian,

Fisheries Branch has reviewed this request to license the continued operation of Pfizer Pharmaceuticals, a pharmaceutical manufacturing facility located at 720 17th St E in the City of Brandon. The facility has been operating since 1966 and it manufactures pharmaceutical quality estrogens by an extraction process from pregnant mare urine with subsequent processing of the extracted estrogens into active pharmaceutical ingredients. Wastewater from the process is trucked to the City of Brandon under an Industrial Discharge License. Process equipment rinse water and sanitary waste is discharged to the City of Brandon's wastewater treatment system. Potable water from the City of Brandon is used at the facility. Containment is provided for the six underground storage tanks that are used for storing bulk materials use in the process and waste materials derived from the process; as well as at the concrete truck pads and; all drums filled with liquid controlled products.

Based on the information provided it would appear that there should limited fisheries concerns with the continued operation of this facility.

Laureen Janusz
Fisheries Science and Fish Culture Section
Fisheries Branch,
Manitoba Conservation and Water Stewardship
Box 20, 200 Saulteaux Crescent
Winnipeg, MB R3J 3W3

Phone: 204.945.7789

Cell: 204.793.1154
Fax: 204.948-2308
Email: Laureen.Janusz@gov.mb.ca

Beshada, Eshetu (CWS)

From: Stibbard, James (CWS)
Sent: May-15-13 1:51 PM
To: Jackson, Adrian (CWS)
Subject: Re: 5647.00 Pfizer Phrmaceuticals Brandon EAP

Mr. Jackson,

I reviewed the above note EAP for an expansion to the Pfizer PMU facility in Brandon. The EAP notes the facility gets water from the City of Brandon water saytem and disposes of wastewater to the City of Brandon sewage treatment facilities.

Based upon this, Office of Drinking Water has no cause for concern with this EAP or the proposed development. I trust this is satisfactory, but if you have any questions, please call.

Regards,

James Stibbard P. Eng.

Approvals Engineer

Office of Drinking Water

1007 Century Street

Winnipeg MB R3H 0W4

phone: (204) 945-5949

fax: (204) 945-1365

email: James.Stibbard@gov.mb.ca

website: www.manitoba.ca/drinkingwater

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Beshada, Eshetu (CWS)

From: Kelly, Jason (CWS)
Sent: May-13-13 8:44 AM
To: Jackson, Adrian (CWS)
Subject: Request for review & comments - Pfizer Pharmaceuticals - Brandon File: 5642.00 - Closing date: May 21, 2013

Parks and Natural Areas Branch has reviewed the proposal filed pursuant to the Environment Act for the Request for review & comments - Pfizer Pharmaceuticals - Brandon File: 5642.00 - Closing date: May 21, 2013. The Branch has no comments to offer as this does not impact any parks or ecological reserves

Jason Kelly, M.N.R.M.
Ecological Reserves and Protected Areas Specialist
Parks and Natural Areas Branch
Conservation and Water Stewardship
Box 53, 200 Saulteaux Cres
Winnipeg, MB R3J 3W3

Phone: 204-945-4148
Cell:
Fax: 204-945-0012

Email: Jason.Kelly@gov.mb.ca

Beshada, Eshetu (CWS)

From: Allison, Sandra (HEALTH)

Sent: May-09-13 10:10 AM

To: Jackson, Adrian (CWS)

Cc: Roberecki, Susan (HEALTH); Roberts, Tracy (HEALTH); Gravelle, Stefane (HEALTH)

Subject: RE: Request for review & comments - Pfizer Pharmaceuticals - Brandon File: 5642.00 - Closing date: May 21, 2013

Hello Adrian,

Our office has reviewed the proposal. Overall, it appears that Pfizer Global Supply (PGS) has addressed most environmental health concerns. Here are a few comments that are worth considering or need to be addressed:

- Page 7, 5th paragraph, 3rd line makes mention of a 'cafeteria' on site that supports production. If this is a facility where meals are prepared for workers, contractors, sub-contractors or visitors to the site, it is defined as a "food handling establishment" under Manitoba Regulation 339/88R under The Public Health Act. Our departmental records and database system indicate that this establishment has not been registered or permitted pursuant to that legislation and has probably gone undetected because it is located inside a secure industrial complex. PGS will be required to register this facility by contacting the Brandon Health Protection Unit Office at (204) 726-6601. The registration form and associated regulation, guidelines are available on-line at: www.manitoba.ca/healthprotection If the 'cafeteria' is a simple lunch room where people consume food they brought from home or ordered in from off site, then a permit is not required, but the status of this facility needs to be clarified with the local Public Health Inspector for the area (726-6601).
- Pages 13 and 17 note the following: some of the emissions are not disclosed as they are classified as 'confidential' pursuant to the 'Proprietary Information Protection Agreement' that is in place. Some of these undisclosed materials are reported as being within 65%-89.9% of air quality limits, which suggests to regulators and the public that limit excursions could occur in the future if industrial processes fail or experience a lapse. The reported emissions from proprietary compounds cannot be commented on as the substances are not known to this reviewer. The reviewer is relying on Conservation staff to understand the proprietary compounds, their health and environmental effects, and the compliance of the emissions of these substances with accepted environmental standards.
- Section VIII.7 on page 17 states that the proponent is not aware of any odour complaints regarding this site during the course of its operations. These portions of the environmental impact statement raise the following questions and/or concerns:
 - a. As a best practices approach, does PGS maintain a log of all reported odour or nuisance complaints and does it confirm that there have been no reported incidents, excursions of odour-nuisance complaints since 1966? Similarly, does Manitoba Conservation record similar events and what does that log indicate? If such a process does not exist, it certainly should be incorporated as a clause in the Environment Act Licence (EAL) and all incidents should be made 'reportable' to Manitoba Conservation and the local Medical Officer of Health.
 - b. Manitoba Conservation operates an ambient air quality monitoring station on the adjacent property at the Assiniboine Community College Campus. This would suggest that there may have been a history of nuisance odours or emissions concerns in the past. If so, what were the concerns and is this station still needed and what parameters are being monitored? Do they include monitoring for the undisclosed emissions associated with 'Materials A-G'? If not, will the EAL formally require PGS to monitor for these emissions and report them on routine basis to Manitoba Conservation? Will the EAL licence prescribe limits for these undisclosed materials/parameters?

- c. PGS has not stated what if any health impacts are generally associated with these undisclosed materials and what type of preventative measures or processes they have in place to prevent or mitigate emissions associated with loss of process control (i.e. reduced production/emissions strategies, treatment/abatement technologies) Will the plant be measuring ambient air in the production facility, for safety of the worker? Will the plant emissions from combustions be monitored routinely?
 - d. What is the formal process that PGS proposes to use in the event that odour complaints are received? A clear & effective process should be outlined in the EAL that involves PGS, Manitoba Conservation officials and the Medical Officer of Health for the area.
- Section Viii,10 Endocrine Disrupting Compounds (EDCs)
 - a. This part of the proposal indicates that wastes are directed to the City of Brandon municipal wastewater treatment facility. While this does not affect PGS' proposal for EA licencing, it does raise the issue of EDCs emissions in the City of Brandon's wastewater effluent being discharged to the environment. Does that EAL contain suitable monitoring, reporting and limits for the effective environmental management of the EDCs and/or related xenoestrogen compounds from other potential sources?

Sandra Allison MD MPH CCFP FRCPC DABPM
Medical Officer of Health
Prairie Mountain Health
20 - 7th Street
Brandon Manitoba
R7A 6M8
Office 204-578-2509
Cell 204-391-3781
Fax 204-578-4950
sandra.allison@gov.mb.ca

and

Stéfane Gravelle, CPHI(C)
Regional Manager
MANITOBA HEALTH
Environmental Health Branch
Health Protection Unit (West/North Region)
340 - 9th Street, Brandon, MB R7A 6C2
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manitoba.ca/healthprotection





Infrastructure and Transportation

Highway Planning and Design Branch
Environmental Services Section
1420 – 215 Garry St., Winnipeg, MB R3C 3P3
T (204) 619-4359 F (204) 945-0593

May 3, 2013

Tracey Braun, M. Sc.
Director, Environmental Approvals Branch
Manitoba Conservation and Water Stewardship
123 Main St., Suite 160
Winnipeg, MB R3C 1A5

RE: Pfizer Pharmaceuticals
Brandon Facility
Client File No 5642.00

Dear Ms. Braun:

MIT has reviewed proposal noted above and we do not have concerns with the development as proposed.

Thank you very much for providing us the opportunity to review the proposal.

Sincerely,

Ryan Coulter, M. Sc., P. Eng.
Manager of Environmental Services

Beshada, Eshetu (CWS)

From: Wiens, Jonathan (CON)

Sent: April-18-13 3:43 PM

To: Jackson, Adrian (CON)

Subject: FW: Request for review & comments - Pfizer Pharmaceuticals - Brandon File: 5642.00 - Closing date: May 21, 2013

Wildlife Branch has no wildlife related concerns.

Jonathan Wiens, MSc

Habitat Specialist

Manitoba Conservation

Box 24 - 200 Saulteaux Crescent

Winnipeg, Manitoba, R3J 3W3

Phone: (204) 945-7764

Mobile: (204) 918-3420

Fax: (204) 945-3077

Email: jonathan.wiens@gov.mb.ca

Beshada, Eshetu (CWS)

Attachments: May 28th Response Email.doc

From: McGregor, Ian [<mailto:Ian.Mcgregor@pfizer.com>]

Sent: May-28-13 8:43 AM

To: Jackson, Adrian (CWS)

Subject: RE: TAC comments

Please see the attachment for PGS Brandon's response to the questions. Our responses are in black. Please contact me should you require additional information or if you have any question regarding our responses.

Ian McGregor

PGS Brandon

Our office has reviewed the proposal. Overall, it appears that Pfizer Global Supply (PGS) has addressed most environmental health concerns. Here are a few comments that are worth considering or need to be addressed:

- 1. Page 7, 5th paragraph, 3rd line makes mention of a ‘cafeteria’ on site that supports production. If this is a facility where meals are prepared for workers, contractors, sub-contractors or visitors to the site, it is defined as a “food handling establishment’ under Manitoba Regulation 339/88R under The Public Health Act. Our departmental records and database system indicate that this establishment has not been registered or permitted pursuant to that legislation and has probably gone undetected because it is located inside a secure industrial complex. PGS will be required to register this facility by contacting the Brandon Health Protection Unit Office at (204) 726-6601. The registration form and associated regulation, guidelines are available on-line at: www.manitoba.ca/healthprotection If the ‘cafeteria’ is a simple lunch room where people consume food they brought from home or ordered in from off site, then a permit is not required, but the status of this facility needs to be clarified with the local Public Health Inspector for the area (726-6601).
 - Thank you for this heads up. We passed this information on to the the operator. The operator submitted an application to Manitoba Health’s Brandon office, a Public Health Inspector has inspected the cafeteria, and we understand that a permit is being processed.

- 2. Pages 13 and 17 note the following: some of the emissions are not disclosed as they are classified as ‘confidential’ pursuant to the ‘Proprietary Information Protection Agreement’ that is in place. Some of these undisclosed materials are reported as being within 65%-89.9% of air quality limits, which suggests to regulators and the public that limit excursions could occur in the future if industrial processes fail or experience a lapse. The reported emissions from proprietary compounds cannot be commented on as the substances are not known to this reviewer. The reviewer is relying on Conservation staff to understand the proprietary compounds, their health and environmental effects, and the compliance of the emissions of these substances with accepted environmental standards
 - Emissions in the Emission Modelling Report were calculated for the maximum emissions at the facility’s maximum production capacity. The calculations represent the “worst case” emissions.

The 65.5% -89.9% emission rates described in the question occur during the unloading of that material into site storage tanks. This represents the “worst case” emissions for those materials. The storage tanks must be vented to allow displacement of the tanks’ headspace during the unloading of the delivery tanker trucks. The tanks are vented for the approximately two hours per load as the material is allowed to gravity flow into the tank. The reported maximum emission rates would be for approximately 8 hours per year for the material estimated at 65.5% of emission rate and approximately 12 hours per year for the material estimated at 89.9% of emission rate. At current production levels emissions would be at the calculated rates for the materials for approximately 2 hours per year for each material.

The unloading of these materials is independent of site processing. Consequently, we consider the likelihood that we would exceed the Ontario limits to be low.

- 3. Section VIII.7 on page 17 states that the proponent is not aware of any odour complaints regarding this site during the course of its operations. These portions of the environmental impact statement raise the following questions and/or concerns:
 - a. As a best practices approach, does PGS maintain a log of all reported odour or nuisance complaints and does it confirm that there have been no reported incidents, excursions of odour-nuisance complaints since 1966? Similarly, does Manitoba Conservation record similar events and what does that log indicate? If such a process does not exist, it certainly should be incorporated as a clause in the Environment Act Licence (EAL) and all incidents should be made 'reportable' to Manitoba Conservation and the local Medical Officer of Health.
 - The PGS Brandon site has a documented site procedure, "Handling Internal and External Environmental Complaints", to receive and document such complaints. PGS Brandon has no record of public complaint of odour or noise at the facility.

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- b. Manitoba Conservation operates an ambient air quality monitoring station on the adjacent property at the Assiniboine Community College Campus. This would suggest that there may have been a history of nuisance odours or emissions concerns in the past. If so, what were the concerns and is this station still needed and what parameters are being monitored? Do they include monitoring for the undisclosed emissions associated with 'Materials A-G'? If not, will the EAL formally require PGS to monitor for these emissions and report them on routine basis to Manitoba Conservation? Will the EAL licence prescribe limits for these undisclosed materials/parameters?
 - No response necessary.
- c. PGS has not stated what if any health impacts are generally associated with these undisclosed materials and what type of preventative measures or processes they have in place to prevent or mitigate emissions associated with loss of process control (i.e. reduced production/emissions strategies, treatment/abatement technologies) Will the plant be measuring ambient air in the production facility, for safety of the worker? Will the plant emissions from combustions be monitored routinely?
 - PGS Brandon follows applicable occupational hygiene guidelines to manage occupational exposures to materials in use at our facility. The Brandon site routinely monitors colleague occupational exposures to the various production materials. The sample collection, analysis and interpretation are conducted by third party certified Occupational Hygienists and laboratories. Occupational hygiene testing results are provided to site colleagues as required under Manitoba Labour regulation.

PGS Brandon maintains an End-Of-Line Condenser on the Plant A production process to collect, chill and condense volatile compounds prior to venting. The collected condensate is sent to organic waste for eventual incineration at a licensed third party hazardous waste incinerator. The Plant B facility collects, condenses and recycles approximately 99.3% of a main proprietary material

thereby reducing air emissions from that process. The site is currently installing a carbon capture system to reduce emissions occurring during the filling of storage tanks, as previously outlined. Storage tanks and process vessels are nitrogen blanketed to reduce material evaporation and therefore emissions. Ventilation in product production areas is equipped with HEPA filtration to prevent the exhaust of particulate pharmaceutically active material.

Natural gas fired boilers, used to provide heat and steam for our facilities, are the only combustion units at the site. The submitted boiler emission data was calculated at the simultaneous operation of all boilers, including backup boilers, at 100% rated capacity.

In light of the foregoing systems, PGS Brandon does not believe additional monitoring is required.

- d. What is the formal process that PGS proposes to use in the event that odour complaints are received? A clear & effective process should be outlined in the EAL that involves PGS, Manitoba Conservation officials and the Medical Officer of Health for the area.
 - As noted previously, the PGS Brandon site has a written procedure to process odour and noise complaints and the site has no records of such complaints. PGS Brandon proposes to incorporate notification to Manitoba Conservation of odour complaints into its existing “Handling Internal and External Environmental Complaints” procedure.
- 4. Section VIII, 10 Endocrine Disrupting Compounds (EDCs)
 - a. This part of the proposal indicates that wastes are directed to the City of Brandon municipal wastewater treatment facility. While this does not affect PGS’ proposal for EA licensing, it does raise the issue of EDCs emissions in the City of Brandon’s wastewater effluent being discharged to the environment. Does that EAL contain suitable monitoring, reporting and limits for the effective environmental management of the EDCs and/or related xenoestrogen compounds from other potential sources?
 - We understand that the City of Brandon is required to implement an EDC monitoring program for its treated wastewater as part of the environmental licensing of the new industrial Waste Water Plant. We believe that The City’s EDC monitoring program will address this comment.