CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211379Orig1s000

OTHER REVIEW(S)

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: September 18, 2019

To: Rachel Ershler, MD, Clinical Reviewer
Division of Hematology Products (DHP)

Patricia Garvey, RPh, Regulatory Project Manager, (DHP)

Virginia Kwitkowski, MS, ACNP-BC, Associate Director for Labeling, DHP

From: Maritsa Serlemitsos-Day, PharmD, BCPS, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Lisa Hubbard, RPh, RAC, Deputy Division Director DAPR I, OPDP

Subject: OPDP Labeling Comments for HEMADY™ (dexamethasone) tablets, for oral use

NDA: 211379

In response to DHP's consult request dated November 4, 2018, OPDP has reviewed the proposed product labeling (PI) for the original NDA submission for HEMADY™ (dexamethasone) tablets, for oral use (Hemady).

OPDP's comments on the proposed labeling are based on the draft PI received by electronic mail from DHP (Patricia Garvey) on September 6, 2019, and are provided below.

Thank you for your consult. If you have any questions, please contact Maritsa Serlemitsos-Day at (301) 796-1760 or maritsa.serlemitsos-day@fda.hhs.gov.

1 Page of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

Reference ID: 4493625

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARITSA SERLEMITSOS-DAY
09/18/2019 01:21:09 PM

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	September 10, 2019
Requesting Office or Division:	Division of Hematology Products (DHP)
Application Type and Number:	NDA 211379
Product Name and Strength:	Hemady (dexamethasone) tablets 20 mg
Applicant/Sponsor Name:	Dexcel Pharma Technologies Ltd. (Dexcel)
FDA Received Date:	September 9, 2019
OSE RCM #:	2018-2295-2
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

1 PURPOSE OF MEMORANDUM

Dexcel submitted revised carton labeling and container label for Hemady (dexamethasone) tablets (Appendix A). The revisions are in response to recommendations that we made during previous label and labeling reviews.[a,b] We reviewed the labels to determine if they are acceptable from a medication error perspective.

2 CONCLUSION

The revised container label and carton labeling are acceptable from a medication error perspective. We have no additional recommendations at this time.

1 Page of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

[a] DeGraw, S. Label and Labeling Review for (b) (4) (dexamethasone) NDA 211379. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 APR 1. RCM No.: 2018-2295.
[b] DeGraw, S. Label and Labeling Review for Hemady (dexamethasone) NDA 211379. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 AUG 20. RCM No.: 2018-2295-1.

Reference ID: 4489604

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

STEPHANIE L DEGRAW
09/10/2019 03:01:51 PM

HINA S MEHTA
09/11/2019 08:48:17 AM

LABEL AND LABELING REVIEW
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	August 20, 2019
Requesting Office or Division:	Division of Hematology Products (DHP)
Application Type and Number:	NDA 211379
Product Name and Strength:	Hemady* (dexamethasone) tablets 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Dexcel Pharma Technologies Ltd. (Dexcel)
FDA Received Date:	June 21, 2019, June 27, 2019 and July 3, 2019
OSE RCM #:	2018-2295-1
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

*The proposed proprietary name, Hemady, is still under review at the time of this review.

Reference ID: 4480233

1. REASON FOR REVIEW

Dexcel Pharma Technologies Ltd. submitted revised labels and labeling as part of a major amendment to NDA 211379 for Hemady (dexamethasone) on June 27 and July 3, 2019, for the treatment of patients with multiple myeloma (MM), as part of combination regimens with anti-myeloma drugs. We evaluate the proposed container label, carton labeling, and Prescribing Information (PI) for areas of vulnerability that could lead to medication errors.

1.1 REGULATORY HISTORY

Dexcel submitted NDA 211379 on September 6, 2018. We reviewed the proposed container label, carton labeling, and PI on April 1, 2019.[a] Dexcel provided a response and updated labels on April 5, 2019.[b] On June 21, 2019, Dexcel submitted a major amendment to provide support for a broader indication.[c] Following the amendment, Dexcel submitted new proposed container label, carton labeling, and PI on June 27 and July 3, 2019.

2. MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

Table 1. Materials Considered for this Label and Labeling Review

Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B – N/A
Human Factors Study	C – N/A
ISMP Newsletters	D – N/A
FDA Adverse Event Reporting System (FAERS)*	E – N/A
Other	F – N/A
Labels and Labeling	G

N/A=not applicable for this review
*We do not typically search FAERS for our label and labeling reviews unless we are aware of medication errors through our routine post-market safety surveillance

[a] DeGraw, S. Label and Labeling Review for (b) (4) (dexamethasone) NDA 211379. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 APR 1. RCM No.: 2018-2295.

[b] Novak, J. Dexcel. Cover Letter – Response to FDA Labeling Recommendations. NDA 211379. 2019 APR 5. \\cdsesub1\evsprod\nda211379\0007\m1\us\12-cover-letter\cover-letter-0007.pdf

[c] Novak, J. Dexcel. Cover Letter – Major Amendment. NDA 211379. 2019 JUN 21. \\cdsesub1\evsprod\nda211379\0009\m1\us\12-cover-letter\cover-letter-0009.pdf

3. OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

We performed a risk assessment of the proposed container label, carton labeling, and prescribing information for Hemady (dexamethasone) to identify deficiencies that may lead to medication errors and other areas of improvement.

Our review of the proposed PI identified areas in the PI, carton labeling and container labels that can be modified to improve the clarity of the information presented.

4. CONCLUSION & RECOMMENDATIONS

DMEPA concludes that the proposed PI and labels can be improved to increase clarity of important information to promote the safe use of the product. We provide recommendations for the division in Section 4.1 and recommendations for Dexcel in Section 4.2 below.

4.1 RECOMMENDATIONS FOR THE DIVISION

A. Highlights of Prescribing Information
    1. Dosage and Administration
        a. As currently presented the dosage statement does not include the frequency of administration. As such, we recommend revising this statement to read, "20 mg or 40 mg orally once daily on specific days depending on the (b) (4) regimen".

B. Section 2 Dosage and Administration
    1. Dosing and Administration Guidelines [2.1]
        a. Revise the 2.1 subheading to read "Recommended Dosage".
        b. To improve clarity, we recommend revising the second sentence to read, "The recommended dosage of HEMADY is 20 mg or 40 mg orally once daily on specific days depending on the treatment regimen".
        c. Revise the 2.2 subheading to read "Dose Modification for Elderly Patients" to reflect the content in the subheading.

C. Section 3 Dosage Forms and Strengths
    1. We recommend revising this statement to read "Tablets: 20 mg white, round, biconvex tablet embossed "20" on one side."

D. Section 16 How Supplied / Storage and Handling
    1. How Supplied [16.1]
        a. We recommend revising this statement to read:
        20 mg tablet: White, round, biconvex tablets embossed "20" on one side.
        NDC 64239-300-10: Bottle of 100
    2. Storage [16.2]
        a. To increase readability, a degree sign should follow each numeric temperature value. We recommend revising this statement to read

Reference ID: 4480233

"Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]".

4.2 RECOMMENDATIONS FOR DEXCEL PHARMA TECHNOLOGIES

A. General Comments

1. We recommend revising the (b) (4) statement to read "Recommended dosage: See prescribing information" to ensure consistency with the Prescribing Information.

B. Container Label

1. We note the barcode currently presented on the container label is an internal manufacture's marking and is not a linear barcode intended for product identification. The drug barcode is often used as an additional verification before drug administration in the hospital setting; therefore, it is an important safety feature that should be part of the label whenever possible. In this case, once the carton is opened, it may be discarded and practitioners will only have the container (bottle) to use for product identification. Therefore, we request you add the product's linear barcode to each individual container as required per 21CFR 201.25(c)(2). When adding a barcode to the container label, we recommend orienting the linear barcode to a vertical position to ensure scannability of the barcode. Barcodes placed in a horizontal position may not scan due to bottle curvature.[d]

[d] Neuenschwander M. et al. Practical guide to bar coding for patient medication safety. Am J Health Syst Pharm. 2003 Apr 15;60(8):768-79.

APPENDICES: METHODS & RESULTS FOR MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for Hemady received on July 3, 2019, from Dexcel Pharma Technologies Ltd. and the listed drug (LD).

Table 2. Relevant Product Information for Hemady and the Listed Drug		
Product Name	Hemady	Decadron[e] [NDA 011664]
Initial Approval Date	N/A	Approved: October 30, 1958 (discontinued, generics available)
Active Ingredient	dexamethasone	dexamethasone
Indication	For the treatment of patients with multiple myeloma (MM), as part of combination regimens with anti-myeloma drugs.	Allergic states Dermatological diseases Diagnostic testing Endocrine disorders Gastrointestinal diseases Hematological disorders Neoplastic diseases Nervous system disorders Ophthalmic diseases Renal diseases Respiratory diseases Rheumatic disorders Trichinosis Tuberculous meningitis
Route of Administration	Oral	Oral
Dosage Form	Tablets	Tablets
Strength	20 mg	0.5 mg and 0.75 mg
Dose and Frequency	The recommended (b) (4) dose in treatment regimens of multiple myeloma is 20 mg or 40 mg, orally, once daily, on specific days of each treatment (b) (4) Refer to the Prescribing Information of the anti-myeloma drugs for specific dexamethasone dosing.	Initial: 0.75 mg to 9 mg per day Max dose in PI: 30 mg per day Dosage requirements are variable and must be individualized based on the disease under treatment and the response of the patient.

[e] Decadron [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2018 APR 23. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/011664s065lbl.pdf.

How Supplied	Supplied as a white, round, biconvex, tablet embossed "20" on one side	Supplied as compressed, pentagonal-shaped tablets 0.5 mg: yellow, coded MSD 41 0.75 mg: bluish-green, coded MSD 63
Storage	Store at 20° to 25°C (68° to 77°F) excursions permitted 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Dispense in a tight, light-resistant, child resistant container.	Controlled room temperature 20 to 25°C (68 to 77°F)
Container Closure	Bottles of 100 tablets	Bottles of 100 tablets

APPENDIX G. LABELS AND LABELING

G.1 List of Labels and Labeling Reviewed

Using the principles of Failure Mode and Effects Analysis,[f] along with post-market medication error data, we reviewed the following Hemady labels and labeling submitted by Dexcel Pharma Technologies Ltd. on July 3, 2019.

- Container Label
- Carton Labeling
- Prescribing Information (no image shown)
  \\cdsesub1\evsprod\nda211379\0011\m1\us\114-labeling\114a-draft-label\11413-pi-draft-labeling-word-tracked.docx

G.2 Labels and Labeling

Container Label

(b) (4)

1 Page of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

[f] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

STEPHANIE L DEGRAW
08/20/2019 05:23:17 PM

HINA S MEHTA
08/21/2019 03:33:12 PM

LABEL AND LABELING REVIEW
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	April 1, 2019
Requesting Office or Division:	Division of Hematology Products (DHP)
Application Type and Number:	NDA 211379
Product Name and Strength:	(b) (4) (dexamethasone) tablets 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Dexcel Pharma Technologies Ltd. (Dexcel)
FDA Received Date:	September 6, 2018, December 10, 2018, and January 16, 2018
OSE RCM #:	2018-2295
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

Reference ID: 4412503

1. REASON FOR REVIEW

Dexcel Pharma Technologies Ltd. submitted a 505(b)(2) NDA 211379 for (b) (4) (dexamethasone) on September 6, 2018. Dexcel Pharma is seeking an indication for us (b) (4) The Division of Hematology Products (DHP) requested DMEPA evaluate the proposed container labels, carton labeling, and Prescribing Information (PI) for areas of vulnerability that could lead to medication errors.

2. MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

Table 1. Materials Considered for this Label and Labeling Review	
Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B – N/A
Human Factors Study	C – N/A
ISMP Newsletters	D
FDA Adverse Event Reporting System (FAERS)*	E – N/A
Other	F – N/A
Labels and Labeling	G

N/A=not applicable for this review
*We do not typically search FAERS for our label and labeling reviews unless we are aware of medication errors through our routine post-market safety surveillance

3. OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

We performed a risk assessment of the proposed container label, carton labeling, and prescribing information for (b) (4) (dexamethasone) to identify deficiencies that may lead to medication errors and other areas of improvement.

Our review of the proposed PI identified the use of an ambiguous symbol (i.e., hyphen) that may cause confusion in Section 2 *Dosage and Administration*. In addition, we identified areas in the PI, carton labeling and container labels that can be modified to improve the clarity of the information presented.

4. CONCLUSION & RECOMMENDATIONS

DMEPA concludes that the proposed PI and labels can be improved to increase clarity of important information to promote the safe use of the product. We provide recommendations for the division in Section 4.1 and recommendations for Dexcel in Section 4.2 below.

4.1 RECOMMENDATIONS FOR THE DIVISION

A. Highlights of Prescribing Information
   1. Dosage and Administration
      a. We recommend revising the (b) (4) dosage statement to remove the hyphens as this can be misinterpreted. Revise to read (b) (4)
      b. Revise (b) (4) and (b) (4) to read (b) (4) and (b) (4)

B. Section 2 Dosage and Administration (b) (4)
   a. We recommend (b) (4) (b) (4) (b) (4)

C. Section 3 Dosage Forms and Strengths
   1. We recommend revising this statement to read "Tablets: 20 mg white, round, biconvex tablet embossed "20" on one side."

D. Section 16 How Supplied / Storage and Handling
   1. How Supplied
      a. We recommend revising this statement to read:
         20 mg tablet: White, round, biconvex tablets embossed "20" on one side.
         NDC 64239-300-10: Bottle of 100"
   2. Storage [16.2]
      a. We recommend revising this statement to read "Store at controlled room temperature 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]."
      b. We recommend adding the statement "Dispense in tight, light resistant container" to be consistent with the container label and carton labeling.

Reference ID: 4412503

4.2 RECOMMENDATIONS FOR DEXCEL PHARMA TECHNOLOGIES

A. General Comments

1. As currently presented, the established name is not in the proper format. Revise the established name to begin with a lower-case letter and should appear inside parentheses (i.e., (dexamethasone)).[a]

2. Dosage Strength
   a. We recommend enlarging the font size of "20 mg" that appears after the established name and deleting the second "20 mg" that is on the bottom of the labels. The strength on the bottom of the principal display panel is duplicative and not necessary.
   b. To improve readability of the strength, ensure there is adequate space between the numerical dose and the unit of measure (i.e., 20 mg instead of 20mg).

3. We recommend revising the (b) (4) statement to read (b) (4) " in accordance with 21 CFR 201.55.

B. Container Label

1. As currently presented, the quantity (100 tablets) appears near the strength (20 mg). We recommend you relocate the net quantity statement away from the product strength, such as to the bottom of the principal display panel. From post-marketing experience, the risk of numerical confusion between the strength and net quantity increases when the net quantity statement is located in close proximity to the strength statement.

2. We recommend reorienting the linear barcode to a vertical position to improve the scannability of the barcode. Barcodes placed in a horizontal position may not scan due to bottle curvature.[b]

3. We recommend decreasing the size of the "Rx Only" statement as this information appears to have the same prominence as the net quantity statement on the principal display panel.

4. As currently presented, the format of the expiration date is not indicated. We recommend that the human-readable expiration date on the drug package label include a year, month, and non-zero day. FDA recommends that the expiration date appear in YYYY-MM-DD format if only numerical characters

[a] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf

[b] Neuenschwander M. et al. Practical guide to bar coding for patient medication safety. Am J Health Syst Pharm. 2003 Apr 15;60(8):768-79.

are used or in YYYY-MMM-DD if alphabetical characters are used to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year and month, to be expressed as: YYYY-MM if only numerical characters are used or YYYY-MMM if alphabetical characters are used to represent the month. FDA recommends that a hyphen or a space be used to separate the portions of the expiration date.

APPENDICES: METHODS & RESULTS FOR MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for (b) (4) received on September 6, 2018, from Dexcel Pharma Technologies Ltd. and the listed drug (LD).

Table 2. Relevant Product Information for (b) (4) and the Listed Drug		
Product Name	(b) (4)	**Decadron**[c] [NDA 011664]
Initial Approval Date	N/A	Approved: October 30, 1958 (discontinued, generics available)
Active Ingredient	dexamethasone	dexamethasone
Indication	For the treatment of patients with (b) (4) multiple myeloma (MM) (b) (4)	Allergic states Dermatological diseases Diagnostic testing Endocrine disorders Gastrointestinal diseases Hematological disorders Neoplastic diseases Nervous system disorders Ophthalmic diseases Renal diseases Respiratory diseases Rheumatic disorders Trichinosis Tuberculous meningitis
Route of Administration	Oral	Oral
Dosage Form	Tablets	Tablets
Strength	20 mg	0.5 mg and 0.75 mg
Dose and Frequency	(b) (4)	Initial: 0.75 mg to 9 mg per day Max dose in PI: 30 mg per day Dosage requirements are variable and must be individualized based on the disease under treatment and the response of the patient.

[c] Decadron [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2018 APR 23. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/011664s065lbl.pdf.

How Supplied	Supplied as a white, round, biconvex, tablet embossed "20" on one side	Supplied as compressed, pentagonal-shaped tablets 0.5 mg: yellow, coded MSD 41 0.75 mg: bluish-green, coded MSD 63
Storage	Controlled room temperature 20 to 25°C (68 to 77°F)	Controlled room temperature 20 to 25°C (68 to 77°F)
Container Closure	Bottles of 100 tablets	Bottles of 100 tablets

APPENDIX D. ISMP NEWSLETTERS

D.1 Methods

On January 29, 2019, we searched the Institute for Safe Medication Practices (ISMP) newsletters using the criteria below, and then individually reviewed each newsletter. We limited our analysis to newsletters that described medication errors or actions possibly associated with the label and labeling.

ISMP Newsletters Search Strategy	
ISMP Newsletter(s)	Acute Care ISMP Medication Safety Alert Community/Ambulatory Care ISMP Medication Safety Alert Nurse Advise-ERR Long-Term Care Advise-ERR ISMP Canada Safety Bulletin Pennsylvania Patient Safety Advisory
Search Strategy and Terms	Match Exact Word or Phrase: dexamethasone

D.2 Results

The search retrieved 18 articles that mentioned dexamethasone; however, there were no relevant articles associated with label and labeling for dexamethasone tablets.

APPENDIX G. LABELS AND LABELING

G.1 List of Labels and Labeling Reviewed

Using the principles of Failure Mode and Effects Analysis,[d] along with post-market medication error data, we reviewed the following (b) (4) labels and labeling submitted by Dexcel Pharma Technologies Ltd.

- Container Label received on January 16, 2019
- Carton Labeling received on January 16, 2019
- Prescribing Information (no image show) received on December 10, 2018. \\cdsesub1\evsprod\nda211379\0001\m1\us\114-labeling\114a-draft-label\11412-pi-annotated-draft-labeling.pdf

G.2 Labels and Labeling

Container Label

(b) (4)

1 Page of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

[d] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

STEPHANIE L DEGRAW
04/01/2019 12:55:58 PM

HINA S MEHTA
04/02/2019 03:09:19 PM

M E M O R A N D U M

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

DATE: 11/7/2018

TO: Division of Hematology Products
Office of New Drugs

FROM: Division of New Drug Bioequivalence Evaluation (DNDBE)
Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct an on-site inspection**

RE: NDA 211379

The Division of Generic Drug Bioequivalence Evaluation (DGDBE) within the Office of Study Integrity and Surveillance (OSIS) determined that an inspection is not warranted at this time for the sites listed below. The rationale for this decision is noted below.

Rationale

(b) (4)

The final classification for the inspections was No Action Indicated (NAI).

Therefore, based on the outcome of the previous inspections and the rationale described above, an inspection is not warranted at this time.

Inspection Sites

Facility Type	Facility Name	Facility Address
Clinical	inVentiv Health Clinique, Inc.	2500 rue Einstein, Quebec City, Quebec, Canada
Clinical	inVentiv Health Clinique, Inc.	5160, boul. Decarie, Suite 800, Montreal, Quebec, Canada
Analytical	(b) (4) .	(b) (4)

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ANGEL S JOHNSON
11/08/2018