Supplemental Information Request from Manitoba Conservation and Water Stewardship regarding RW Packaging's Environment Act Proposal

Questions received from Manitoba Conservation and Water Stewardship and the answers to them (in blue) are provided below.

1. List of liquid and powder raw materials with MSDS.
   A list of the raw materials used in 2015 is provided in Table S.1. The MSDSs for each of the materials listed are provided in the folder accompanying this document.
   a. Volume processed per year.
      The amounts vary from year to year depending on the orders received. The amounts of raw material used in 2015 are listed in Table S.1
   b. Volume stored on-site at any given time.
      The amounts stored on site at any particular time vary according to the amount and formulation requirements of the product being manufactured. The maximum amount of Isopropyl Alcohol 99% and Rubbing Alcohol that could be stored is the capacity of their respective holding tanks; 2 x 26,000 L tanks and 1 x 26,000 L tank, respectively.

2. Is the powder received readymade for the formulation or processed at RW Packaging?
   The powders received are ready made for the formulation. They are received in sealed containers appropriately sized for the formulation.

3. List the kind of waste picked up by Miller Environmental.
- Organic and laboratory chemical wastes are picked up by Miller Environmental on a semi-annual basis. Organic wastes consist of mineral oil, castor oil, and eucalyptus oil.
- Hydraulic oils.
- Lab wastes consist of alcohol, peroxide, acids and bases.
- Printer ink and solvent.

4. Provide how the formulated drugs that failed a QA/QC are handled.
   Please see attached Procedure (Out of Specification Procedure).

5. Provide information where labels are printed.
   Printed ready-to-use labels are supplied by a third party vendor.

6. Provide information how recalled products are handled.
   Please see attached Procedure (Recall Procedures).

Table S.A.1 Amounts of material used in 2015.

Raw Material	Unit	Amount used in 2015
Allantoin Powder	Kg	1.0
Anise Oil	Gram	652.5
Bentonite Powder	Kg	1,402.6
Calamine powder	Kg	5,831.5
Calcium Hydroxide	Kg	94.5
Camphor Powder	Kg	7.4
Castor Oil	Litre	10,975.0
Dendritic Salt	Kg	28,736.6
Dillweed Oil	Gram	11,880.6
Dye, Red	Kg	0.0
Epsom Salts	Kg	2,915,985.9
Ethyl Alcohol	Litre	4,691.0
Eucalyptus Oil	Litre	5,504.7
Fragrance, Cosmo Joe Fresh Vanilla & Shea Butter	Kg	84.7
Fragrance, Givaudin Joe Fresh Eucalyptus/Spearmint	Kg	362.2
Fragrance, Givaudin Joe Fresh Lavender	Kg	736.1
Fragrance, Givaudin Joe Fresh Tangerine	Kg	81.3
Fragrance, Givaudin Joe Fresh Ylang/Ylang & Vanilla	Kg	71.1
Fragrance, Rose	Kg	3.0
Glycerine	Kg	37,269.5
Hydrogen Peroxide 50%	Kg	40,126.0
Iodine	Kg	58.6
Alcohol Isopropyl alcohol 99%	Litre	813,210.7
Jojoba Oil	Litre	1.6
Menthol	Kg	194.6
Methyl Paraben Sodium (Nipagin M)	Gram	75,470.9
Mineral Oil Puretol 35 USP	Kg	71,903.7
Mineral Oil Puretol 7 USP	Kg	12,071.1
Oil Fennel FCC	Gram	632.2
Oil Of Clove (Stem) F.C.C.	Kg	30.2
Olive Oil - food grade	Litre	1,797.6
Peppermint Spirits	Litre	7.3
Potassium Iodide	Kg	58.6
Propyl Paraben Sodium (Nipasol M)	Gram	60,031.4
Propylene Glycol	Kg	36.8

Rubbing Alcohol	Litre	146,603.7
Sodium Bicarbonate	Kg	726.6
Sugar Granulated	Kg	8,068.8
Tween 80	Kg	237.0
Witch Hazel	Litre	52,162.9
Zinc Oxide Powder	kg	6,426.2

Out of Specification Procedure

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define RW Packaging's policy concerning: the importance given to the integrity of quality testing and documentation records and to describe the necessary actions to be taken to investigate an Out-of-Specification (OOS) test result.

2.0 SCOPE

This procedure applies to all testing results of: raw materials, packaging materials, in-process materials, and finished products; including validation and stability performed in the manufacturing of drug products at RW Packaging Ltd. This procedure also extends to all test results from outside contract laboratories used by RW Packaging Ltd.

3.0 DEFINITIONS

Out-of-Specification Result (OOS): An individual test value that does not meet the predetermined specification. Out-of-specification results obtained in the laboratory fall into three general categories:

(1) Laboratory error:
- a) Analyst's mistake:
  - Mistakes in calculations or weights,
  - Undetected cross contamination,
  - Use of incorrect solutions or standards,
  - Simple mismeasurement,
  - Lack of training and/or skills.
- b) Malfunctioning/uncalibrated laboratory equipment.

(2) Non-process related or operator error:
- a) Manufacturing equipment malfunction,
- b) Operator failure to follow procedure or add the proper amount of an ingredient.

(3) Process related or manufacturing error:
- a) Incorrect mixing time in procedure,
- b) Incorrect specification or test method.

OOS Investigation: An investigation that follows an out-of-specification result, this can be either an Initial or a Full Investigation.

Initial Investigation: The Initial Investigation attempts to determine if the laboratory has made an error. The initial investigation is done within the laboratory that generated the OOS result and only includes the analyst who generated the OOS result.

Full Investigation: A Full Investigation is done after inconclusive initial investigations, or multiple out-of-specification test results, which may be the result of a non-process or process related error that potentially could affect all batches of a product or multiple products. A Full Investigation attempts to decide where the root cause originates, prompting corrective action and to prevent reoccurrence.

Resample: Physically taking another representative sample from the original material sampled. Resampling can only be done if (1) the pharmacopoeial standard allows for it, (2) the investigation discloses evidence the original sample is not representative or (3) the sample was improperly prepared or insufficient material exists for a retest.

Retest: Repeating the test on a second aliquot from the original sample; the first option.

Specification: Related names include: acceptance criteria, tolerances, limits, quality standards and requirements. Specifications are set to ensure a product will meet regulatory, customer and design requirements after the product has been shipped and until its expiry date. Meeting specifications is a major activity of production and quality control. Several elements will influence the settings of specifications. These include: USP/pharmacopoeial requirements, label claims, safety, efficacy, stability profiles, statistical methods, validated methods & Health Canada audits/expectations. Product/process variability within and between batches, sources of variability, fitness for use, customer needs or desires, regulatory comfort level (risk), material & manufacturing costs, expert opinions, & similar competitor products.

4.0 RESPONSIBILITIES

4.1 It is the responsibility of the Quality Control Specialist to ensure that this SOP is performed as described and to maintain the required documentation for Initial Investigations.

4.2 It is the responsibility of Manager of Quality Assurance to assure that this SOP is performed as described and to lead in Full Investigations.

4.3 All other departments are responsible for providing the highest priority participation in Full Investigations at the direction Manager of Quality Assurance.

5.0 PROCEDURE

5.1 Within 24 working hours, the Quality Control Specialist is to review the test set-up for any obvious physical reason for the out-of-specification result. If any are found, record the reason(s), invalidate the test and retest.

5.2 When no physical reason is found for the OOS results then retest the original sample. If the second test result meets specification then record both values (reporting the first value as analyst error) in the lab book and record the last value on the Certificate of Analysis.

5.3 If results are out of specification then conduct an Initial laboratory investigation for possible causes reviewing the notebook, equipment and activities and completing an Initial Investigation Report.

5.4 <u>INITIAL INVESTIGATION</u> (Within the laboratory)

5.4.1 The first phase of an investigation is the initial assessment of the accuracy of the original laboratory data. Frequent errors suggest a problem that might be due to inadequate training of analysts, equipment malfunction, expired solutions or standards, non-validated test methods or unreliable or incorrect specifications. Whenever laboratory error is identified an NCR is to be issued to prompt corrective action and reduce the probability of reoccurrences.

5.4.2 If the original sample is found to not be representative, finish the investigation, invalidate the data, resample and test again. Document the Conclusions section in the report.

5.4.3 If an analyst error is found, retest the original sample. If the second test result meets specification, finish the investigation; record both values in the lab book and record the second result on the Certificate of Analysis. Document in the Conclusions section in the report. If the results are not within specification,

begin a Full Investigation.

5.4.4 If another reason is found for the OOS result, retest the original sample. If the second test result meets specification, finish the investigation; record both values in the lab book and record the second result on the Certificate of Analysis. Document in the Conclusions section in the report. If the results are not within specification, begin a Full Investigation.

5.4.5 If no reason is found for the OOS result, the review is inconclusive. Manager of Quality Assurance should then make a justifiable decision to (1) retest or (2) not retest.

5.4.6 If a decision is made to retest then the original sample will be retested 3 times, if enough material remains. If the second set of results are in specification, finish the investigation; record all values in the lab book. Fully document the decision and the specific rationale to retest. Document in the Conclusions section in the report.

5.4.7 If any of the second results are also suspect, begin a Full Investigation. If a decision to retest cannot be justified, begin a Full Investigation.

5.4.8 Inconclusive Initial Investigations are to be reported in writing to Manager of Quality Assurance no later than the next working day.

5.5 FULL INVESTIGATION

5.5.1 When the initial investigation does not determine that laboratory error caused the OOS result and testing results appear to be accurate a Full Investigation is to be conducted to identify the source of the OOS result. The investigation is to be led by Manager of Quality Assurance in conjunction with Senior Management and will consist of a timely, thorough, and well-documented review of the entire process (eg, manufacturing process for formulated product).

5.5.2 Manager of Quality Assurance will do a initial review of the manufacturing equipment and batch records for obvious physical evidence for the multiple out-of-specification results. (eg. Ingredient not added, not mixed as long as required).

5.5.3 If physical evidence is found, record the reason(s), complete the investigation and invalidate the data. An NCR is to be issued and corrective action taken and documented. Resample and retest to the specifications.

5.5.4 When no physical evidence is found for the OOS results, and there is no reason to believe the OOS results are the result of any failures anywhere in the system, it may be appropriate to resample and retest. This decision is to be justified and documented by Manager of Quality Assurance. The number of resamples, locations and retests will be specified in advance of testing and a decision made on those results.

5.5.5 If all of the additional results are within specification and not dissimilar from the

historical data, then all data is to be reported in the Full Investigation report. All data is to be used to make a decision about the situation.

5.5.6 If any of the additional results are out of specification or unusual in the context of historical data, a Full Investigation for physical reasons will begin again and continue until a scientifically justifiable explanation with valid data is established.

5.5.7 Normal operation is suspended until resolution. The batch in question is to be rejected. When an explanation is presented and accepted a corrective course of action may be developed and implemented.

5.5.8 Only after any corrective action is completed, may normal operations restart. All activities, findings and data are to be reported in the Full Investigation Report. An active monitoring system shall be initiated and maintained until the situation is understood and unchanging.

6.0 RECORDS

6.1 All test data is to be recorded in lab books. Un-validated test results are to be crossed out, initialed and supported with an explanation. Completed "Initial Investigation" and "Full Investigation" reports are to be numbered and maintained in the OOS Investigation Log Book located in the Laboratory.

6.2 Copies of all reports are to distributed to the President & CEO

6.3 All reports, corrective actions and follow-up activities are discussed at Management Review Meetings.

7.0 ASSOCIATED DOCUMENTS

7.1 Initial Investigation Report (RWP - QR 143)
7.2 Full Investigation Report (RWP – QR 144)
7.3 Non Conformance Report (RWP – QR 11)
7.4 Corrective Action Request (RWP – QR 116)

8.0 REFERENCES

8.1 FDA Guideline. "Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production," Sept/98
8.2 "Out-of-Specifications Basics", Torbeck & Associates Inc. 2002
8.3 QMP – 022 "Control of Non conforming product"
8.4 QMP – 024 "Corrective and Preventive Action"

Recall Procedures

1.0 PURPOSE

1.1 To provide RW Packaging Ltd. with a detailed written recall system that will permit a rapid and effective product recall. This will include the identification of all internal and external personnel involved in the recall action, their functions and responsibilities; the channels and means of communication and the control of returned stock, etc.

1.2 Applies to all products manufactured and/or distributed by RW Packaging Ltd. The Company will also cooperate and assist all contract manufacturing customers (ie, Citron Remedies, Country Connections) with any recall involving their products.

2.0 DEFINITIONS

2.1 Product means any "DIN'ed" or "NPN'ed" product manufactured and/or distributed by RW Packaging Ltd.

2.2 Drug Products means any "DIN'ed "product manufactured and/ or distributed by RW Packaging Ltd.

2.3 Effectiveness Checks The purpose of conducting effectiveness checks is to verify that all customers specified by the Recall Plan have received notification about the Company's decisions and have taken appropriate action. The method for contacting customers for effectiveness checks may be accomplished by telephone calls, written communications, or a combination thereof.

2.4 Recall with respect to a product means a firm's removal from further sale or use, or correction, of either a marketed drug product that violates legislation administered by the Health Protection Branch or a product (intended for Internal Use) that does not meet the associated regulatory requirements.

2.5 Product withdrawal means a firm's removal from further sale or use, or correction of a marketed product where there is no health and safety risk and no contravention of the legislation. It is not considered to be a recall.

2.6 Stock Recovery means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm. It is not considered to be a recall.

2.7 Recall Classification means the numerical designation, i.e. Class I, Class II or Class III, assigned to a particular drug product recall to indicate the relative degree of health hazard presented by the product being recalled.

- Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

- Class II is a situation in which the use of, or exposure to, a violative product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

- Class III is a situation in which the use of, or exposure to, a violative product is not likely to cause any adverse health consequences.

3.0 RESPONSIBILITIES

3.1 General Manager has the primary responsibility for initiating a Recall Committee Meeting and act as the Recall Coordinator (when necessary).

3.2 The Recall Committee is responsible to assess the situation and, if a Recall is deemed necessary, implement and direct the Recall Plan. The Recall Committee is composed of Senior Management and a member of the Quality team.

The members of the Recall Committee are as follows:

Title	Name	Telephone #
President & CEO	Henry De Ruiter	780 965 4142
VP & General Manager	Mei Chung-Lewis	204 296-9792
Executive VP-Finance/Administrat/Assurance	Bernice Ryzowski	204 510-6014
Quality Assurance/Regulatory Coordinator	Svetlana Saks	204-786-6873 ext:224
Director of Sales	Jeff Sherman	780-935-2141

3.3 Any person aware of a potential recall situation shall contact a member of the Recall Committee in writing immediately. All departmental managers have the responsibility of implementing the Recall Plan in accordance with the decisions made by the Recall Committee.

4.0 PROCEDURE

4.1 Before initiating a recall all known information on the nature and extent of the reputed health hazard will be gathered, correlated and evaluated. Simultaneously, a quarantine of all inventory and any scheduled shipments of the suspect product will be made pending the decision of the Recall Committee.

4.2 Health Hazard Evaluation and Risk Assessment

4.2.1 A Recall Committee meeting is to be held to evaluate the health hazard presented by a product considered for recall and will take into account, but need not be limited to, the following factors:

a) Whether any disease or injuries have already occurred from the use of the product.
b) Assessment of the hazard to people who are expected to be exposed to the product.
c) Assessment of the degree of seriousness of the health hazard.
d) Assessment of the likelihood of occurrence of the hazard.
e) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

4.2.2 Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

4.2.3 The Recall Committee will evaluate all the information and define the Company Plan including:

a) whether the product is subject to a Stock Recovery, Product Withdrawal or Recall
b) the level of Effectiveness Checks (see 5.5)
c) Company personnel authorized to make decisions on behalf of the Company for this particular recall
d) Depending on the product's degree of hazard and the extent of distribution, the Company Plan will specify the level in the distribution chain to which the decision is to extend and the type of written notification(s) the Company will issue to all distribution channels of products manufactured by RW Packaging Ltd; including wholesalers, distributors and retailers (if necessary).

4.2.4 All Recall Committee decisions are to be kept in writing and properly filed.

4.3 Recall Communications

4.3.1 The format, content, and extent of the recall communication should be commensurate with the hazard of the product being recalled. The purpose of a recall communication is to convey:

1. That the product in question is subject to a recall.
2. That further distribution or use of any remaining product should cease immediately;
3. Where applicable and required as part of the recall strategy, that the direct account should in turn notify its accounts that received the product about the recall;
4. Instructions regarding what to do with the product.

4.3.2. A recall communication must include the following features:

1. Notify each customer promptly
2. Be written in the two official languages (French and English);
3. Be brief and to the point;
4. Identify clearly the product, brand name(s), size, lot number(s), or code(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
5. Explain concisely the reason for the recall and the hazard involved;
6. Provide specific instructions on what should be done with respect to the recalled product;
7. Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product along with a specific timeframe for a response.

4.3.3. As determined by the Recall Plan, a recall communication can only be accomplished in writing through a "Recall Notice". The communication should also be marked: "Urgent" for Class I and Class II recalls.

4.3.4 Customer specified requirements regarding the recall of a Private Label product such as for Shoppers Drug Mart, Loblaws & Safeway must be referenced and followed. Their designated contact or recall coordinator must be contacted and be involved in all aspects of a recall involving their product.

4.3.5. A second written communication is needed in Class I or Class II Recalls to notify the next level of the distribution chain (retail level). This communication is to include:

- Recall notification (same information as in 5.3.2)
- Logistics information (such as how and where to return products, consolidation of freights, carriers to use). This information needs to be consented between customers and the Company's Sales Dept.

4.4 Notification to Health Canada (In the case of a Drug Product)

4.4.1. It is imperative that before or upon initiating a "recall" only, the local Health Canada Inspectorate be notified in writing.
For Drugs (DIN): This notice should be provided to the Inspectorate **within 24 hours** of having made the decision to recall. This must be followed by a written report **within 3 business days** of initiating the action containing sufficient information to enable Health Canada to assess risk to health.
For Natural Health Products (NPN): The information should be provided to the Inspectorate **within 3 days** after the day on which the recall is commenced.
The basic information required to include the following:

a) The name and description of the recalled product, the DIN or NPN number, the lot number and any other means of identification.
b) The total quantity of the recalled product manufactured and/or packaged.
c) The total quantity of the recalled product that had been distributed up to the time of the recall.
d) Area of the distribution of the recalled product by province.
e) The quantity of the recalled product under quarantine.
f) The reason for initiating the recall.

4.5 Effectiveness Checks

4.5.1. The Recall Committee will specify the level of effectiveness checks that will be conducted, based on the seriousness of the situation. For Drug products, 100% (hundred percent) of the total number of customers are to be contacted. For other products a variable percentage of the total number of customers will be contacted, which percentage is to be determined on a case-by-case basis, but always greater than 10% (ten percent).

4.5.2. The Effectiveness Check is supervised by the Recall Coordinator and conducted within 5 (five) working days from the first written Recall Communication issued by the Company.

4.5.3. When customers have responded in writing to the Recall Notice, this may be considered a positive response.

4.5.4. Effectiveness Check results are to be kept in writing and filed as part of the Recall file.

4.6 Product Returns & Conciliation

4.6.1 Reports on stock inventories, sales transactions & customer lists pertaining to the product being recalled are to be generated. Using these reports, original source documents (work orders for production and shipping reports for customers' shipments) are pulled from files that identify and verify product activity by lot. In addition all quality control documentation and any correspondence that has occurred is to be compiled for evaluation by the Recall Committee.

4.6.2. All returns along with the documentation of returns received of the recalled product to any RW Packaging Ltd. facility will be sent to the attention of the Recall Coordinator.

4.6.3. All returned products are to be verified and kept properly identified and isolated from any other products.

4.6.4. A physical count will be conducted when all the recalled product is received back.

4.7 Termination of a Product Recall

4.7.1. A recall will be terminated when the Recall Committee of RW Packaging Ltd. is satisfied that the product subject to the recall has been removed and proper disposition or correction has been made. In the case of a recall involving a drug product the Health Canada Inspectorate must be in agreement before the termination takes effect.

4.8 Final Report of Recall

4.8.1. Upon completion of the recall, the Recall Committee shall prepare a final report. In the case of a drug recall, a copy will be sent to the Health Canada Inspectorate .The report shall contain the following:

i) All possible causative factors leading to the recall.
ii) Efficacy of the recall including a final reconciliation.
iii) Corrective and/or preventative actions taken or to be implemented.
iv) Recommendations for additions and/or modifications to the existing Quality System Procedures.
v) Reference to all reports, documents, correspondence & minutes pertaining to the recall.

4.9 Disposition

4.9.1 After the final evaluation of the problem all affected product will be accounted for, corrected or disposed properly according to regulatory requirements.

5.0 RECORDS

5.1 All records, minutes and documentation are to be maintained and filed in accordance with procedure QMP-004 "Control of Quality Records".

6.0 REFERENCES

6.1 Product Recall Procedure – HPFB Inspectorate 2002-05-23

6.2 GMP-2009

6.3 Health Products and Food Branch Inspectorate- Recall Policy (POL-0016)

7.0 ASSOCIATED DOCUMENTS

7.1 Recall Log Book (RWP-QR-79)