NDA 212690/S-006
NDA 021196/S-036

SUPPLEMENT APPROVAL

Jazz Pharmaceuticals Ireland Limited
Attention: Arthur Merlin d'Estreux, M.Sc.
Director, Global Regulatory Lead – Neurosciences
One Commerce Square
2005 Market Street
Philadelphia, PA 19103

Dear Mr. d'Estreux:

Please refer to your supplemental new drug applications (sNDAs) dated February 12, 2021, received February 12, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for XYWAV™ (calcium, magnesium, potassium, and sodium oxybates) oral solution and NDA 21196 Xyrem (sodium oxybate) oral solution.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated February 26, 2021.

The Prior Approval supplemental new drug application 212690/S-006 provides for the new indication of Idiopathic Hypersomnia (IH) for XYWAV. NDA 212690/S-006 and NDA 021196/S-036 provide for modifications to the approved XYWAV and XYREM risk evaluation and mitigation strategy (REMS) to align with the revisions to the XYWAV prescribing information.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA (NDA 212690), including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for XYREM was originally approved on February 27, 2015, and the REMS for XYWAV was approved on July 21, 2020. The two drugs are subject to the same REMS, known as the XYWAV and XYREM REMS. The most recent REMS modification was approved on February 11, 2021. The REMS consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS consist of:

- Changes to the REMS materials to align with the new indication of Idiopathic Hypersomnia for XYWAV
- Changes to the REMS assessment timetable

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

- Change of the reporting interval for the Knowledge, Attitude, and Behavior Surveys from annually to every other year.

In accordance with section 505-1 of the FDCA, we have determined that the following REMS modifications are necessary to ensure the benefits of the drug outweigh the risks:

- Changes to the ***Patient Counseling Checklist*** to capture additional information regarding concomitant medication and alcohol use.

Your proposed modified REMS, submitted on February 12, 2021, amended and appended to this letter, is approved.

The timetable for submission of assessments of the REMS has been revised. Jazz Pharmaceuticals must submit a REMS Assessment on April 26, 2022, and annually thereafter.

The revised REMS assessment plan must include, but is not limited to, the following:

Program Implementation and Operations

1. REMS Enrollment Statistics (per reporting period and cumulatively)
    a. Patients:
        i. Number and percentage of newly enrolled patients stratified by age, geographic region (defined by US Census), indication, and gender
        ii. Number and percentage of active patients enrolled (patients who received at least one shipment of XYWAV or XYREM during the reporting period) stratified by age, geographic region (defined by US Census), and gender
        iii. Number and percentage of patients who have discontinued XYWAV or XYREM after receiving at least one shipment of XYWAV or XYREM. Include demographics of discontinued patients and reasons for discontinuation.
        iv. Number and percentage of patients who transitioned from XYREM to XYWAV
        v. Number and percentage of patients who transitioned from XYWAV to XYREM.
    b. Healthcare Providers:
        i. Number and percentage of newly certified healthcare providers stratified by professional designation (i.e. MD, DO, PA, NP), medical specialty, and geographic region (defined by US Census)

ii. Number and percentage of active certified healthcare providers (healthcare providers who have written at least one prescription for XYWAV or XYREM during the reporting period) stratified by professional designation (i.e. MD, DO, PA, NP), medical specialty, and geographic region (defined by US Census)
iii. Number of patients by current enrolled prescriber.

c. Certified Pharmacy
i. If the Certified Pharmacy was decertified during the reporting period and reasons for decertification.

2. Utilization Data (per reporting period and cumulatively)
a. Number and percentage of XYREM prescriptions (new and refills) dispensed
b. Number and percentage of XYWAV prescriptions (new and refills) dispensed
c. Number and percentage of XYREM bottles and shipments sent
d. Number and percentage of XYWAV bottles and shipments sent.

3. REMS Program Operation and Performance Data (per reporting period and cumulatively)
a. REMS Program Central Database Report
i. Number and percentage of contacts by stakeholder type (e.g. patients, healthcare providers, pharmacy, other)
ii. Summary of reasons for contacts (e.g., enrollment questions) by reporter (authorized representative, patient, healthcare provider, other)
iii. Call center report with number of calls received and a summary of reasons for calls by stakeholder type
iv. Summary of frequently asked questions by stakeholder type and topic
v. Summary of any REMS-related problems identified and a description of any corrective actions taken
vi. If the summary reason for the calls indicates a complaint, provide details on the nature of the complaint(s) and whether they indicate potential REMS burden or patient access issues
vii. Summary of program or system problems and a description of any corrective actions taken.

4. REMS Program Compliance (per reporting period and cumulatively)
a. Audits: Summary of audit activities including but not limited to:
i. A copy of the audit plan for each audited stakeholder.
ii. The number of audits expected, and the number of audits performed
iii. The number and type of deficiencies noted

iv. For those with deficiencies noted, report the status of corrective and preventative action (CAPA) proposed to address the deficiencies. The status to include completion status.
v. For any that did not complete the CAPA within the timeframe specified in the audit plan, describe actions taken
vi. Provide details on deviations for the CAPA proposed, including timelines, and mitigating steps to address the deviations
vii. Confirm documentation of completion of training for relevant staff
viii. Review of accumulative findings to identify any trends of potential repeat issues, and steps to be taken to address these findingsA summary report of the processes and procedures that are implemented to be in compliance with the REMS requirements.

b. A summary report of noncompliance, associated corrective and preventive actions (CAPA) plans, and the status of CAPA plans including but not limited to:
    i. A copy of the Noncompliance Plan which addresses the criteria for noncompliance for each stakeholder, actions taken to address noncompliance for each event, and under what circumstances a stakeholder would be suspended or de-certified from the REMS
    ii. The number of instances of noncompliance accompanied by a description of each instance and the reason for the occurrence (if provided). For each instance of noncompliance, report the following information:
        1) The unique ID(s) of the stakeholder(s) associated with the noncompliance event or deviation to enable tracking over time
        2) The source of the noncompliance data
        3) The results of root cause analysis
        4) What action(s) were taken in response.
c. Healthcare Providers
    i. Number and percentage of certified prescribers who were disenrolled during the reporting period and reasons for disenrollment. Include if any prescribers were re-certified.
    ii. Number of disenrolled prescribers who were associated with a XYWAV and XYREM prescription and number of disenrolled prescribers associated with a XYWAV and XYREM shipment

iii. Number and percentage of XYWAV prescriptions filled from a prescriber who was not enrolled.
iv. Number and percentage of XYREM prescriptions filled from a prescriber who was not enrolled.

d. Certified Pharmacy
   i. Number and percentage of XYWAV prescriptions dispensed for more than a 30 days' supply (first fill) or more than a 90 days' supply (refills) and reasons
   ii. Number and percentage of XYREM prescriptions dispensed for more than a 30 days' supply (first fill) or more than a 90 days' supply (refills) and reasons
   iii. Number and percentage of XYWAV shipments lost in delivery (and unrecovered) with number of DEA 106 Forms and Risk Management Reports (RMRs) completed
   iv. Number and percentage of XYREM shipments lost in delivery (and unrecovered) with number of DEA 106 Forms and Risk Management Reports (RMRs) completed
   v. Number and percentage of initial XYWAV shipments sent to patients without completion of the XYWAV and XYREM REMS Patient Counseling Checklist.
   vi. Number and percentage of initial XYREM shipments sent to patients without completion of the XYWAV and XYREM REMS Patient Counseling Checklist.

e. Patients
   i. Number and percentage of patients who were disenrolled from the program and reasons for disenrollment
   ii. Number and percentage of patients associated with more than one prescriber during their therapy
   iii. Number and percentage of patients prescribed a daily dose of XYWAV of >9 g
   iv. Number and percentage of patients prescribed a daily dose of XYREM of >9 g
   v. Number and percentage of patients with overlapping prescriptions (more than one active prescription shipped)
   vi. Number and percentage of patients with concurrent XYWAV and XYREM prescriptions
   vii. Number of duplicate patients detected by the Certified Pharmacy

viii. Number and percentage of duplicate patients who were shipped XYWAV or XYREM under more than one name or identifier

ix. Number and percentage of patients who were shipped XYWAV or XYREM after being disenrolled

x. Number and percentage of patients who requested an early refill of XYWAV and reason for the request
   1) Number and percentage of requests approved
   2) Number and percentage of requests denied by the prescriber
   3) Number and percentage of requests denied by the Certified Pharmacy
   4) Number and percentage of patients with multiple requests for early refills.

xi. Number and percentage of patients who requested an early refill of XYREM and reason for request
   1) Number and percentage of requests approved
   2) Number and percentage of requests denied by the prescriber
   3) Number and percentage of requests denied by the Certified Pharmacy
   4) Number and percentage of patients with multiple requests for early refills.

Safe Use Behaviors

5. Pharmacy Notifications (per reporting period and cumulatively, for both XYWAV and XYREM)
   a. A summary of the notifications by pharmacies to prescribers for both XYWAV and XYREM. For each of the following situations, include the number and percentage of notifications, number of unique patients, the outcome of the pharmacy notification (e.g. counseled patient, discussed with prescriber and prescriber's designee) and outcome of XYWAV and XYREM prescription disposition (e.g. prescriber approved shipment, prescriber requested shipment hold, prescriber denied shipment, pharmacy approved shipment):
      i. Use with sedative-hypnotics indicated for sleep (e.g., eszopiclone, zaleplon, zolpidem, temazepam, suvorexant, quazepam, estazolam, flurazepam, triazolam, tasimelteon, ramelteon). Indicate specific actions taken by the prescriber and the prescriber rationale for continuing treatment in response to the notification including the following:
         - Treatment with XYWAV /XYREM will discontinue
         - Sedative hypnotic will be discontinued

- Dosage of sedative hypnotic has been/will be reduced
- Information unavailable
- No action (continue sedative hypnotic with XYWAV or XYREM)
- Prescriber's rationale for continued use of sedative hypnotic with XYWAV or XYREM
    - Sedative hypnotic will not be taken at the same time asXYWAV /XYREM
    - Sedative hypnotic will be taken at the same time as XYWAV /XYREM
    - Sedative hypnotic will be taken as a sleep aid
    - Sedative hypnotic will be taken for different indication per medical need
    - XYWAV /XYREM dose regimen changed
    - No rationale provided

ii. Benzodiazepines (e.g., diazepam, alprazolam or any not listed in metric 5.a.i.). Indicate specific actions taken by the prescriber and the prescriber rationale for continuing treatment in response to the notification including the following:

- Treatment with XYWAV /XYREM will discontinue
- Benzodiazepine will be discontinued
- Dosage of benzodiazepine has been/will be reduced
- Information unavailable
- No action (continue benzodiazepine with XYWAV or XYREM)
- Prescriber's rationale for continued use of benzodiazepine with XYWAV or XYREM
    - Benzodiazepine will not be taken at the same time as XYWAV /XYREM
    - Benzodiazepine will be taken at the same time as XYWAV /XYREM
    - Benzodiazepine will be taken as a sleep aid
    - Benzodiazepine will be taken for different indication per medical need
    - XYWAV /XYREM dose regimen changed
    - No rationale provided

iii. Use with other concomitant CNS-depressant medications (sedating antidepressants or antipsychotics, sedating anti-epileptics, sedating antihistamines, general anesthetics, muscle relaxants, opioid analgesics, or illicit CNS depressants)
iv. Patient report of alcohol use
v. Patient report of diagnosis of sleep apnea
vi. Patient report of diagnosis of asthma, COPD, or other conditions affecting breathing
vii. Suspected abuse, misuse, or diversion
viii. Alerts regarding potential abuse, misuse, or diversion on the patient profiles
ix. Prescription error
x. Early refill requests

6. Risk Management Reports (RMRs) (per reporting period and cumulatively, for both XYWAV and XYREM)
    a. Number and percentage of RMRs submitted
    b. Number and percentage of unique patients with a RMR
    c. Number and percentage of unique patients with multiple RMRs
    d. Number and percentage of alerts generated from RMRs
    e. Number and percentage of RMRs generated from early refill requests
    f. Number and percentage of RMRs generated for other reasons (list reasons)
    g. Number and percentage of prescriber-related RMRs
    h. Number and percentage of RMRs that included an adverse event.
7. REMS Program Patient Counseling Checklist (per reporting period and cumulatively, for both XYWAV and XYREM)
    a. Summary table for both XYWAV and XYREM from REMS Program Patient Counseling Checklists of the number and percentage of patients taking the following concomitant medications and who subsequently received at least one shipment of drug:
        i. Sedative hypnotics indicated for sleep (e.g., eszopiclone, zaleplon, zolpidem, temazepam, suvorexant, quazepam, estazolam, flurazepam, triazolam, tasimelteon, ramelteon)
        ii. Alcohol
        iii. Other potentially interacting agents:
            - Benzodiazepines (e.g., diazepam, alprazolam or any not listed in metric 7.a.i.)
            - Sedating antidepressants or antipsychotics, sedating anti epileptics, and sedating antihistamines
            - General anesthetics
            - Muscle relaxants

- Opioid analgesics
- Divalproex sodium or other valproate drug (e.g.,valproic acid)
- Illicit CNS depressants (e.g., heroin or gamma-hydroxybutyrate [GHB]).

b. Summary tables for both XYWAV and XYREM from REMS Program Patient Counseling Checklists of the number and percentage of patients who have been diagnosed with the following conditions and who subsequently received at least one shipment of drug:
c. Sleep apnea
d. Asthma, COPD, or other conditions affecting the respiratory system.

Health Outcomes and/or Surrogates of Health Outcomes

8. Pharmacovigilance/surveillance (per reporting period)
   a. Separate summary tables for XYWAV and XYREM of the number of reports of serious adverse events. The summary tables will include the following data fields (CIOMS II line listings): date, report ID, report type, notifier, age, gender, indication, start and stop date, dose, frequency, onset date, system organ class, outcome, and causality. All tables should include an overall narrative summary of the adverse events and data fields reported.
      i. All cases of death
         1) Number, percentage, and type of RMRs, notifications, and alerts associated with any reported deaths.
      ii. All outcomes of death, emergency department visits (when admitted to hospital), or hospitalizations resulting from or associated with the following:
         1) Use with concurrent sedative hypnotics and alcohol. Provide a breakdown of concomitant sedative hypnotics usage (ex. zolpidem=6%, eszopiclone=3%)
         2) Intentional misuse
         3) Abuse
         4) Overdose
         5) Medication error
      iii. Cases of sexual abuse
      iv. Proportion of discontinued patients who were associated with a report of a serious adverse event, including death.

Knowledge

9. Knowledge, Attitude, and Behavior (KAB) Surveys of Patients, Caregivers, and Healthcare Providers (to be submitted every other year beginning with the April 2023 assessment)
    a. Assessment of patients'/caregivers' and healthcare providers' understanding of the following:
        i. The risk of significant CNS and respiratory depression associated with XYWAV and XYREM even at recommended doses
        ii. The contraindicated uses of XYWAV and XYREM
        iii. The potential for abuse, misuse, and overdose associated with XYWAV and XYREM
        iv. The safe use, handling, and storage of XYWAV and XYREM
        v. The XYWAV and XYREM REMS Program requirements.
10. Knowledge, Attitude, and Behavior (KAB) Surveys of Pharmacists (to be submitted every other year beginning with the April 2023 assessment)
    a. Assessment of pharmacists' understanding of the following:
        i. The risk of significant CNS and respiratory depression associated with XYWAV and XYREM even at recommended doses
        ii. The contraindicated uses of XYWAV and XYREM
        iii. The potential for abuse, misuse, and overdose associated with XYWAV and XYREM
        iv. The safe use, handling, and storage of XYWAV and XYREM
        v. The XYWAV and XYREM REMS Program requirements.
11. Certified Pharmacy knowledge assessments (per reporting period and cumulatively)
    a. Number of pharmacy staff who completed post-training knowledge assessments including method of completion and the number of attempts needed to complete.
        i. Provide a breakdown of scores within Module A and B
    b. Summary of the most frequently missed post-training knowledge assessment questions
    c. Summary of potential comprehension or perception issues identified with the post-training knowledge assessment by module
    d. Number of pharmacy staff who did not pass the knowledge assessments.

12. The requirements for assessments of an approved REMS under section 505-1 (g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each

element of the strategy, is meeting the goal or whether one or more such goals or such elements should be modified.

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved REMS, you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the REMS, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit a supplemental application for a new indication for use, as described in section 505-1(g)(2)(A) of the FDCA. This assessment should include:

a) An evaluation of how the benefit-risk profile will or will not change with the new indication;

b) A determination of the implications of a change in the benefit-risk profile for the current REMS;

c) *If the new indication for use introduces unexpected risks*: A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.

d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use*: A statement about whether the REMS was meeting its goals at the time of that last assessment and if any modifications of the REMS have been proposed since that assessment.

e) *If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* Provision of as many of the currently listed assessment plan items as is feasible.

f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including*: Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications*, provide a rationale for why the REMS does not need to be modified.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA ###### REMS ASSESSMENT METHODOLOGY
(insert concise description of content in bold capital letters, e.g., ASSESSMENT METHODOLOGY, PROTOCOL, SURVEY METHODOLOGIES, AUDIT PLAN, DRUG USE STUDY)

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA ###### REMS ASSESSMENT

or

NEW SUPPLEMENT FOR NDA ######/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA ######/S-000
PRIOR APPROVAL SUPPLEMENT

PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA ######/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING CHANGES SUBMITTED IN SUPPLEMENT XXX

or

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA ######/S-000
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISIONS FOR NDA ######

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, or website screenshots are only in PDF format, they may be submitted as such, but Word format is preferred.

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

FDA can accept the REMS document in Structured Product Labeling (SPL) format. If you intend to submit the REMS document in SPL format, as soon as possible, but no later than 14 days from the date of this letter, submit the REMS document in SPL format using the FDA automated drug registration and listing system (eLIST).

For more information on submitting REMS in SPL format, please email FDAREMSwebsite@fda.hhs.gov.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-*

Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Teresa Wheelous, Regulatory Project Manager, at teresa.wheelous@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Eric Bastings, MD
Acting Director
Division of Neurology 1
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

- REMS

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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/

TERESA J BURACCHIO on behalf of ERIC P BASTINGS
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