DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021372
NDA 022233

WRITTEN REQUEST – AMENDMENT 3

Helsinn Healthcare SA
C/O August Consulting, Inc.
Attention: Craig Lehmann, Pharm.D.
Authorized Representative
515 S. Capital of Texas Hwy., Suite #150
Austin, TX 78746

Dear Dr. Lehmann:

Please refer to your correspondence dated January 17, 2013, requesting changes to FDA's July 23, 2010 Written Request for pediatric studies for palonosetron hydrochloride.

We have reviewed your proposed changes and are amending the below-listed sections of the Written Request. All other terms stated in our Written Request issued on July 23, 2010, and as amended on September 30, 2010 and October 22, 2012, remain the same. (Text added is underlined. Text deleted is strikethrough.)

BACKGROUND:
Per 2006 American Society of Clinical Oncology (ASCO) guidelines on antiemetics, commonly administered moderately emetogenic (MEC) and highly emetogenic (HEC) chemotherapeutic agents are administered intravenously to pediatric patients (e.g., doxorubicin, daunorubicin, cyclophosphamide, carboplatin, ifosfamide, cisplatin, cyclophosphamide, dactinomycin, doxorubicin). Given that pediatric chemotherapy patients typically have intravenous access and the delivery of oral medications to this patient population may cause emesis, the use of an orally administered palonosetron formulation for CINV prevention will be very limited. ~~However, the availability of a pharmacy compounded palonosetron liquid preparation for oral administration would be beneficial to those pediatric chemotherapy patients who lack intravenous (I.V.) access.~~

- *Drug information:*
  - *regimen*

    Study 4: CINV

    ☐ The PK data may be collected in a subset of patients to obtain data for the palonosetron dose(s) and age groups for which data are not available from previously conducted pediatric CINV studies. The PK data from this study and previously conducted palonosetron pediatric CINV studies may be pooled to assess the PK parameters for 3 palonosetron doses in the full range of pediatric ages. The C_{max} values following either the 15 minute infusion or 30 second bolus may be reported using a population PK

analysis as appropriate. The protocol for the PK study and planned pooled PK analysis must be submitted and receive Division concurrence prior to the start of the study.

Use an age-appropriate formulation in the studies described above. If an age-appropriate formulation is not currently available, you must develop and test an age-appropriate formulation and, if it is found safe and effective in the studied pediatric population(s), you must seek marketing approval for that age-appropriate formulation. ~~The formulation must be appropriately packaged and marketed for the intended route.~~

For ease of reference, a complete copy of the Written Request, as amended, is attached to this letter.

Reports of the studies that meet the terms of the Written Request dated July 23, 2010, as amended by this letter and by previous amendment dated September 30, 2010 and October 22, 2012, must be submitted to the Agency on or before January 13, 2014, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

Submit reports of the studies as supplements to an approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, clearly mark your submission **"SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED"** in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. In addition, send a copy of the cover letter of your submission, via fax (240-276-9327) or messenger, to the Director, Office of Generic Drugs, HFD-600, Metro Park North IV, 7519 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, submit proposed changes and the reasons for the proposed changes to your application. Clearly mark submissions of proposed changes to this request **"PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. We will notify you in writing if we agree to any changes to this Written Request.

If you have any questions, call Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Attachment: Complete Clean Copy of Written Request as amended

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WRITTEN REQUEST

Helsinn Healthcare SA
C/O August Consulting, Inc.
Attention: Craig Lehmann, Pharm.D.
Authorized Representative
515 S. Capital of Texas Hwy., Suite #150
Austin, TX 78746

Dear Dr. Lehmann:

Reference is made to your February 14, 2007 Proposed Pediatric Study Request for Aloxi (palonosetron hydrochloride).

BACKGROUND:
These studies investigate the potential use of palonosetron hydrochloride in the prevention of postoperative nausea and vomiting (PONV) and chemotherapy induced nausea and vomiting (CINV) in pediatric patients.

The literature has documented that pediatric patients experience both PONV and CINV. The vast majority of PONV and CINV prevention therapies prescribed to children have been poorly studied in the pediatric population. Drug utilization data indicate that palonosetron is being prescribed off-label to prevent nausea and vomiting in pediatric patients undergoing treatment for malignancy or in patients with symptoms of unspecified etiology.

Per 2006 American Society of Clinical Oncology (ASCO) guidelines on antiemetics, commonly administered moderately emetogenic (MEC) and highly emetogenic (HEC) chemotherapeutic agents are administered intravenously to pediatric patients (e.g., doxorubicin, daunorubicin, cyclophosphamide, carboplatin, ifosfamide, cisplatin, cyclophosphamide, dactinomycin, doxorubicin). Given that pediatric chemotherapy patients typically have intravenous access and the delivery of oral medications to this patient population may cause emesis, the use of an orally administered palonosetron formulation for CINV prevention will be very limited.

To obtain needed pediatric information on palonosetron hydrochloride, the Food and Drug Administration (FDA) is hereby making a formal Written Request, pursuant to Section 505A of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Food and Drug Administration Amendments Act of 2007, that you submit information from the following studies.

- **Nonclinical study(ies):**
  Based on review of the available non-clinical toxicology, no additional animal studies are required at this time to support the clinical studies described in this Written Request.

- **Clinical studies:**
  - *Types of studies:*
    Study 1: PONV Safety and Efficacy Study – a multicenter, double-blind, randomized, study in pediatric patients 1 month to less than 17 years of age

    Study 2: CINV Pharmacokinetic, Safety and Efficacy Study – a multicenter, double-blind, randomized, study in pediatric patients 2 to less than 18 years of age, with an open-label cohort of patients 1 month to less than 2 years of age

    Study 3: PONV Safety and Efficacy Study – an adequate, well-controlled, randomized, parallel-group trial of palonosetron administered intravenously
    - ☐ Efficacy in pediatric patients cannot be extrapolated from adult efficacy, and will be determined by the studies outlined in the Written Request.

    Study 4: CINV Pharmacokinetic (PK), Safety and Efficacy Study – an adequate, well-controlled, randomized, parallel-group trial of more than one dose level of palonosetron administered intravenously
    - ☐ This study must include a palonosetron dose greater than 10 mcg/kg.
    - ☐ The active comparator administered to pediatric patients, including patients < 6 months old, must be consistent with the standard of care for CINV prevention (e.g., ondansetron).
    - ☐ This study must collect safety data in pediatric patients for at least 3 chemotherapy cycles. Although not a requirement of this Written Request, additional safety data should be collected in pediatric patients receiving a fourth chemotherapy cycle.
    - ☐ The safety and efficacy portion of Study 4 must be blinded.
    - ☐ Efficacy in pediatric patients cannot be extrapolated from adult efficacy, and will be determined by the studies outlined in the Written Request.

  - *Objective of each study:*
    Study 1: PONV – To provide proof of concept for a single dose of I.V. palonosetron for the prevention of PONV in pediatric surgical patients.

    Study 2: CINV – To determine pharmacokinetic parameters of I.V. palonosetron and provide proof of concept for a single dose to prevent chemotherapy induced nausea and vomiting in pediatric patients receiving both MEC and HEC.

    Study 3: PONV – To evaluate the safety and efficacy of I.V. palonosetron for the prevention of PONV in pediatric surgical patients compared to standard therapy

    Study 4: CINV – To evaluate the PK parameters, safety and efficacy of I.V. palonosetron for the prevention of CINV in pediatric cancer patients receiving MEC or HEC compared to standard therapy

- *Patients to be Studied:*
  - *Age group in which studies will be performed*:
    Study 1: PONV – Age 1 month to < 17 years divided into four age groups:
    < 2 years
    2 to < 6 years
    6 to < 12 years
    12 to < 17 years

    Study 2: CINV – Age 1 month to < 18 years divided into four age groups:
    < 2 years
    2 to < 6 years
    6 to < 12 years
    12 to < 18 years

    Study 3: PONV – Age 0 to < 17 years divided into four age groups:
    < 2 years
    2 to < 6 years
    6 to < 12 years
    12 to < 17 years

    Study 4: CINV – Age 0 to < 17 years divided into four age groups:
    < 2 years
    2 to < 6 years
    6 to < 12 years
    12 to < 17 years

  - *Number of patients to be studied:*
    Study 1: PONV – Approximately 150 patients

    Study 2: CINV – Approximately 70 patients

    Study 3: PONV – The number of patients should be distributed approximately evenly among the four age groups to the extent possible. Diligent and reasonable efforts must be made to encourage enrollment across all age groups, including younger patients, and these efforts must be documented in the study report.

    Study 4: CINV – For the PK component, there must be a minimum of 24 patients per age group for PK sampling for the 2 to <6, 6 to <12, and 12 to 17 year old groups and a minimum of 15 patients for PK sampling for the 0 to <2 year old group. The PK data from this study must be combined with data from other relevant studies to provide descriptive statistics for each age group.

    Timing of blood samples must be such that the pharmacokinetic parameters can be adequately characterized. A population PK approach may be used. The total number of study patients should be distributed approximately evenly among the four age groups to the extent possible. Diligent and reasonable efforts must be made to encourage

enrollment across all age groups, including younger children, and these efforts must be documented in the study report.

Representation of Ethnic and Racial Minorities: The studies must take into account adequate (e.g., proportionate to disease population) representation of children of ethnic and racial minorities. If you are not able to enroll an adequate number of these patients, provide a description of your efforts to do so and an explanation for why they were unsuccessful.

- *Study endpoints:*
  - ☐ *Pharmacokinetic Endpoints:*
    - ☐ Study 2: CINV – For each age group outlined above, the pharmacokinetic endpoints must include C_{max}, T_{max}, AUC, $T_{1/2}$, clearance, and Vd.
    - ☐ Study 3: PONV – PK parameters should be evaluated for neonates, if enrollment is possible.
    - ☐ Study 4: CINV – The pharmacokinetic endpoints must include C_T (concentration at end of infusion for intravenous formulation), C_{max}, T_{max}, AUC, $T_{1/2}$, clearance, and Vd.
  - ☐ *Efficacy Endpoints:*
    - ☐ Study 1: PONV – The analysis must include the efficacy endpoint of Complete Response (no vomiting, no retching, and no use of rescue medication) from 0 to 24 hours.
    - ☐ Study 2: CINV – The analysis must include the efficacy endpoint of Complete Response (no vomiting, no retching, and no use of rescue medication) from 0 to 24 hours (acute phase) after the first chemotherapy dose is administered in the first chemotherapy cycle.
    - ☐ Study 3: PONV – The primary efficacy endpoint must be Complete Response (no vomiting, no retching, and no use of rescue medication) from 0 to 24 hours.
    - ☐ Study 4: CINV – The primary efficacy endpoint must be Complete Response (no vomiting, no retching, and no use of rescue medication) from 0 to 24 hours after the first chemotherapy dose is administered in the first chemotherapy cycle. A key secondary efficacy endpoint must be Complete Response (no vomiting, no retching, and no use of rescue medication) from > 24 to 120 hours (delayed phase) after the first chemotherapy dose is administered in the first chemotherapy cycle.
    - ☐ Studies 3 & 4: PONV and CINV (in the first chemotherapy cycle) – Additional secondary endpoints must include the following.
      - No vomiting
        - PONV Study - from 0 to 24 hours
        - CINV Study – from 0 to 24 hours, from > 24 to 120 hours, and overall (0 to 120 hours)
      - Use of antiemetic rescue medication
      - Time to rescue
      - Time to first vomiting episode

- ☐ *Safety Endpoints:*
  - ☐ Studies 1 & 2: PONV and CINV– Safety
  - ☐ Studies 3 & 4: PONV and CINV (for chemotherapy cycles 1, 2, and 3) – Safety outcomes must include adverse events (recorded and summarized), physical examinations, vital signs (including blood pressure), 12-lead electrocardiogram, and clinical laboratory assessments (including electrolytes and serum liver enzymes). Safety data from the CINV Study also is expected to support the safety of palonosetron for PONV prevention in pediatric patients.
  - ☐ All adverse events must be monitored.
  - ☐ A Data Monitoring Committee (DMC) must be established because the studies will be conducted in children, a potentially fragile population. See the Guidance: Establishment and Operation of Clinical Trial Data Monitoring Committees http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126578.pdf

- *Known Drug Safety concerns and monitoring:* Palonosetron undergoes renal and hepatic elimination. In Studies 3 and 4, carefully monitor infusion site reactions including thrombophlebitis in studies of the I.V. formulation. Based on identification of new post-market safety information, monitoring of infusion site reactions was incorporated for Studies 3 and 4.

- *Extraordinary results:* In the course of conducting these studies, you may discover evidence to indicate that there are unexpected safety concerns, unexpected findings of benefit in a smaller sample size, or other unexpected results. In the event of such findings, there may be a need to deviate from the requirements of this Written Request. If you believe this is the case, you must contact the Agency to seek an amendment. It is solely within the Agency's discretion to decide whether it is appropriate to issue an amendment.

- *Drug information:*
  - *dosage form* – age appropriate formulation
  - *route of administration* – intravenous
  - *regimen*

    Study 1: PONV
    - ☐ A single palonosetron dose will be given prior to surgery.

    Study 2: CINV
    - ☐ A single palonosetron dose will be given prior to the initiation of MEC or HEC chemotherapy.

    Study 3: PONV
    - ☐ A single palonosetron dose will be given prior to surgery.
    - ☐ Dose selection must be based on:
      - clinical and PK data for palonosetron in adult surgical patients and pediatric oncology patients,
      - clinical data for palonosetron in pediatric surgical patients, and

- the ontogeny of CYP450 enzymes involved in the disposition of palonosetron.

These data and a summary analysis justifying palonosetron dose selection must be reported to the Agency prior to the initiation of the study.

Study 4: CINV

- ☐ A single palonosetron dose will be given prior to the initiation of MEC or HEC chemotherapy.
- ☐ Dose selection must be based on clinical and PK data from the use of palonosetron in adult and pediatric cancer patients and the ontogeny of CYP450 enzymes involved in the disposition of palonosetron. These data and a summary analysis justifying palonosetron dose selection must be reported to the Agency prior to the initiation of the study.
- ☐ The use of corticosteroids should be based on recognized standard of care in CINV prevention in pediatric cancer patients receiving MEC/HEC and should be administered as determined by the investigator.
- ☐ The PK data may be collected in a subset of patients to obtain data for the palonosetron dose(s) and age groups for which data are not available from previously conducted pediatric CINV studies. The PK data from this study and previously conducted palonosetron pediatric CINV studies may be pooled to assess the PK parameters for 3 palonosetron doses in the full range of pediatric ages. The C_{max} values following either the 15 minute infusion or 30 second bolus may be reported using a population PK analysis as appropriate. The protocol for the PK study and planned pooled PK analysis must be submitted and receive Division concurrence prior to the start of the study.
- ☐ Randomization of patients 1 month to 2 years old to doses higher than 10 mcg/kg must be justified based on PK-PD and tolerability data available in this age group prior to the start of the study. The Division must agree with the planned doses prior to the start of the study.
- ☐ A PK and Tolerability Sub-study should be conducted in pediatric patients 0 to 1 month old to assess exposure and tolerability in this age group. You must justify the dose for this sub-study based on available data on known developmental differences in neonates that may affect disposition of palonosetron. You should seek to enroll at least 3 patients in this initial PK and Tolerability Sub-study. If there is adequate justification based on the sub-study data, additional neonates may be enrolled to an appropriate dose level. The Division must agree with the planned sub-study dose and any higher study doses for 0 to 1 month olds prior to the start of the study(ies).

Use an age-appropriate formulation in the studies described above. If an age-appropriate formulation is not currently available, you must develop and test an age-appropriate formulation and, if it is found safe and effective in the studied pediatric population(s), you must seek marketing approval for that age-appropriate formulation.

In accordance with section 505A(e)(2), if

1) you develop an age-appropriate formulation that is found to be safe and effective in the pediatric population(s) studied (i.e., receives approval);

2) the Agency grants pediatric exclusivity, including publishing the exclusivity determination notice required under section 505A(e)(1) of the Act; and
3) you have not marketed the formulation within one year after the Agency publishes such notice,

the Agency will publish a second notice indicating you have not marketed the new pediatric formulation.

Bioavailability of any formulation used in the studies must be characterized, and as needed, a relative bioavailability study comparing the approved drug to the age appropriate formulation may be conducted in adults.

- *Statistical information, including power of studies and statistical assessments:*
  Study 1: PONV – Descriptive statistics

  Study 2: CINV – Descriptive statistics

  Study 3: PONV – The protocol must provide a statistical analysis plan for assessing efficacy and safety. For the primary endpoint analysis, the study must enroll a sufficient number of patients to provide at least 80% power with a non-inferiority margin of 10% at an alpha level of 2.5% one-sided test (equivalent to 5% 2-sided test) to reject the null hypothesis that the study drug is inferior to active control drug by more than the non-inferiority margin. You must clearly state the null and alternative hypotheses in your study protocol. Primary endpoint analysis stratified by age group is recommended. The protocol must be submitted and receive Division concurrence prior to the start of the study.

  Study 4: CINV – The study protocol must include a plan for evaluating PK parameters. Additionally, the final study report must provide appropriate analyses and descriptive statistics for all PK data consistent with the four age groups noted earlier.

  The protocol must provide a statistical analysis plan for assessing efficacy and safety. For the primary efficacy endpoint, the study must enroll a sufficient number of patients to provide at least 80% power (all age groups combined) with a non-inferiority margin of 15% at an alpha level of 2.5% in a one-sided test (equivalent to 5.0% 2-sided test) to reject the null hypothesis that the study drug is inferior to the active control drug by more than the non-inferiority margin. You must clearly state the null and alternative hypotheses in your study protocol. The primary endpoint analysis should be stratified by age group and chemotherapy type (HEC or MEC). The protocol must be submitted and receive Division concurrence prior to the start of the study.

- *Labeling that may result from the studies*: You must submit proposed pediatric labeling to incorporate the findings of the studies. Under section 505A(j) of the Act, regardless of whether the studies demonstrate that palonosetron hydrochloride is safe and effective, or whether such study results are inconclusive in the studied pediatric population(s) or subpopulation(s), the labeling must include information about the results of the studies. Under section 505A(k)(2) of the Act, you must distribute to physicians and other health care providers at least annually (or

more frequently if FDA determines that it would be beneficial to the public health), information regarding such labeling changes that are approved as a result of the studies.

- *Format and types of reports to be submitted*: You must submit full study reports (which have not been previously submitted to the Agency) that address the issues outlined in this request, with full analysis, assessment, and interpretation. In addition, the reports must include information on the representation of pediatric patients of ethnic and racial minorities. All pediatric patients enrolled in the studies should be categorized using one of the following designations for race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander or White. For ethnicity, you should use one of the following designations: Hispanic/Latino or Not Hispanic/Latino. If you choose to use other categories, you should obtain agency agreement.

  Under section 505A(d)(2)(B) of the Act, when you submit the study reports, you must submit all postmarketing adverse event reports regarding this drug that are available to you at that time. All post-market reports that would be reportable under section 21 CFR 314.80 should include adverse events occurring in an adult or a pediatric patient. In general, the format of the post-market adverse event report should follow the model for a periodic safety update report described in the Guidance for Industry E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs and the Guidance addendum. You are encouraged to contact the reviewing Division for further guidance.

  Although not currently required, we request that study data be submitted electronically according to the Study Data Tabulation (SDTM) standard published by the Clinical Data Interchange Standards Consortium (CDISC) provided in the document "Study Data Specifications," which is posted on the FDA website at http://www.fda.gov/CDER/REGULATORY/ersr/Studydata.pdf and referenced in the FDA Guidance for Industry, *Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at http://www.fda.gov/Cder/guidance/7087rev.htm.

- *Timeframe for submitting reports of the studies:* Reports of the above studies must be submitted to the Agency on or before January 13, 2014. Please keep in mind that pediatric exclusivity attaches only to existing patent protection or exclusivity that would otherwise expire nine (9) months or more after pediatric exclusivity is granted, and FDA has 180 days from the date that the study reports are submitted to make a pediatric exclusivity determination. Therefore, to ensure that a particular patent or exclusivity is eligible for pediatric exclusivity to attach, you are advised to submit the reports of the studies at least 15 months (9 months plus 6 months/180 days for determination) before such patent or exclusivity is otherwise due to expire.

- *Response to Written Request:* Under section 505A(d)(2)(A)(i), within 180 days of receipt of this Written Request you must notify the Agency whether or not you agree to the Written Request. If you agree to the request, you must indicate when the pediatric studies will be initiated. If you do not agree to the request, you must indicate why you are declining to conduct the studies. If you decline on the grounds that it is not possible to develop the appropriate pediatric formulation, you must submit to us the reasons it cannot be developed.

Furthermore, if you agree to conduct the studies, but have not submitted the study reports on or before the date specified in the Written Request, the Agency may utilize the process discussed in section 505A(n) of the Act.

Submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission "**PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC EXCLUSIVITY STUDY**" in large font, bolded type at the beginning of the cover letter of the submission.

Reports of the studies should be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF PEDIATRIC STUDY REPORTS - PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED**" in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. Please also send a copy of the cover letter of your submission to the Director, Office of Generic Drugs, HFD-600, Metro Park North IV, 7519 Standish Place, Rockville, MD 20855-2773. If you wish to fax it, the fax number is 240-276-9327.

In accordance with section 505A(k)(1) of the Act, *Dissemination of Pediatric Information*, FDA must make available to the public the medical, statistical, and clinical pharmacology reviews of the pediatric studies conducted in response to this Written Request within 210 days of submission of your study report(s). These reviews will be posted regardless of the following circumstances:

1. the type of response to the Written Request (i.e. complete or partial response);
2. the status of the application (i.e. withdrawn after the supplement has been filed or pending);
3. the action taken (i.e. approval, complete response); or
4. the exclusivity determination (i.e. granted or denied).

FDA will post the medical, statistical, and clinical pharmacology reviews on the FDA website at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM049872

If you wish to discuss any amendments to this Written Request, please submit proposed changes and the reasons for the proposed changes to your application. Submissions of proposed changes to this request should be clearly marked "**PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. You will be notified in writing if any changes to this Written Request are agreed upon by the Agency.

Please note that, if your trial is considered an "applicable clinical trial" under section 402(j)(1)(A)(i) of the Public Health Service Act (PHS Act), you are required to comply with the provisions of section 402(j) of the PHS Act with regard to registration of your trial and submission of trial results. Additional information on submission of such information can be found at www.ClinicalTrials.gov.

If you have any questions, call Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JULIE G BEITZ
02/15/2013