CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213150Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND 123631

MEETING PRELIMINARY COMMENTS

Tolmar Therapeutics, Inc.
Attention: Michelle R. Ryder
Vice President, Regulatory Affairs
701 Centre Avenue
Fort Collins, CO 80526

Dear Ms. Ryder:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for leuprolide acetate for injectable suspension, 45 mg.

We also refer to your October 16, 2018, correspondence, requesting a meeting to discuss your proposed NDA application for the treatment of central precocious puberty.

Our preliminary responses to your meeting questions are enclosed.

You should provide, to the Regulatory Project Manager, a hardcopy or electronic version of any materials (i.e., slides or handouts) to be presented and/or discussed at the meeting.

In accordance with 21 CFR 10.65(e) and FDA policy, you may not electronically record the discussion at this meeting. The official record of this meeting will be the FDA-generated minutes.

If you have any questions, call me at (301) 796-2194.

Sincerely,

{See appended electronic signature page}

Jennifer Johnson
Regulatory Health Project Manager
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE: Preliminary Meeting Comments

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PRELIMINARY MEETING COMMENTS

Meeting Type:	Type B
Meeting Category:	Pre-NDA
Meeting Date and Time:	Monday, January 14, 2019; 12:00 – 1:00 pm EST
Meeting Location:	Teleconference
Application Number:	IND 123631
Product Name:	leuprolide acetate for injectable suspension, 45 mg
Indication:	Treatment of central precocious puberty
Sponsor Name:	Tolmar Therapeutics, Inc.

FDA ATTENDEES (tentative)

Division of Metabolism and Endocrinology Products

Lisa Yanoff, M.D.	Acting Director
William Chong, M.D.	Acting Deputy Director for Safety
Marina Zemskova, M.D.	Clinical Team Leader
Shannon Sullivan, M.D., PhD	Acting Clinical Team Leader
Todd Bourcier, Ph.D.	Pharmacology/Toxicology Supervisor
Jeffrey Quinn, Ph.D.	Pharmacology/Toxicology Reviewer
Pamela Lucarelli	Chief, Project Management Staff
Jennifer Johnson	Regulatory Health Project Manager

Office of Clinical Pharmacology, Division of Clinical Pharmacology 2

Jaya Vaidyanathan, Ph.D.	Clinical Pharmacology Team Leader
Justin Penzenstadler, Ph.D.	Clinical Pharmacology Reviewer

Office of Pharmaceutical Quality
Office of New Drug Products

Donna Christner, Ph.D.	Branch Chief, Division of New Drug API
Danae Christodoulou, Ph.D.	Branch Chief, New Drug Product Division 2

Office of Biostatistics, Division of Biometrics 2

Roberto Crackel, Ph.D.	Statistics Reviewer
Sara Jimenez, Ph.D.	Acting Statistics Team Leader

Office of Surveillance and Epidemiology

Deveonne Hamilton-Stokes, RN, BSN, MA	Safety Regulatory Project Manager

SPONSOR ATTENDEES

Representing Tolmar, Inc.

Avinash Nangia, Ph.D.	Chief Scientific Officer
John A. McLane, Ph.D.	Vice President of Clinical Development
Michelle Ryder	Vice President, Regulatory Affairs
Renu Gambhir, Ph.D.	Director Regulatory Affairs, Proprietary Products

Introduction:
This material consists of our preliminary responses to your questions and any additional comments in preparation for the discussion at the meeting scheduled for Monday, January 14, 2019, at 12:00 pm EST between Tolmar Therapeutics, Inc. and the Division of Metabolism and Endocrinology Products. We are sharing this material to promote a collaborative and successful discussion at the meeting. The meeting minutes will reflect agreements, important issues, and any action items discussed during the meeting and may not be identical to these preliminary comments following substantive discussion at the meeting. However, if these answers and comments are clear to you and you determine that further discussion is not required, you have the option of cancelling the meeting (contact the regulatory project manager (Jennifer Johnson)). If you choose to cancel the meeting, this document will represent the official record of the meeting. If you determine that discussion is needed for only some of the original questions, you have the option of reducing the agenda and/or changing the format of the meeting (e.g., from face to face to teleconference). It is important to remember that some meetings, particularly milestone meetings, can be valuable even if the pre-meeting communications are considered sufficient to answer the questions. Contact the RPM if there are any major changes to your development plan, the purpose of the meeting, or the questions based on our preliminary responses, as we may not be prepared to discuss or reach agreement on such changes at the meeting.

1.0 BACKGROUND

The sponsor is developing this product, a synthetic nonapeptide analog of naturally occurring gonadotropin releasing hormone (GnRH) agonist, for the treatment of central precocious puberty (CPP) in children. It is to be administered subcutaneously, one injection every 6 months. Note: this product is approved under NDA 021731 in the Division of Oncology Products 1 (in the Office of Hematology and Oncology Products) for the palliative treatment of advanced prostate cancer (ELIGARD 45 mg/6 Months).

The sponsor has conducted a single pivotal study TOL2581A, entitled, “An Open-label, Two-dose, Non-comparative, Multicenter Study on the Efficacy, Safety, and Pharmacokinetics of Leuprolide Acetate 45 mg 6-month Formulation in Subjects with Central (Gonadotropin-dependent) Precocious Puberty.” Enrolled subjects were treated with an injection of leuprolide acetate 45 mg (the approved 6-month formulation) at baseline, followed by an additional injection 6 months later. Periodic safety and efficacy assessments were conducted for 12 months following the first injection. The sponsor has included a synopsis and schedule of assessments for Protocol TOL2581A in the briefing package. No nonclinical studies are planned.

The sponsor plans to submit the results of Study TOL2581A as a New Drug Application (NDA) via the 505(b)(2) regulatory pathway.

On July 30, 2014, the sponsor requested a Pre-IND meeting to discuss development plans for this product, and a Meeting Minutes – Written Responses Only (WRO) letter was issued on September 29, 2014.

On October 16, 2018, the sponsor requested a Pre-NDA meeting to discuss their proposed NDA application for the treatment of central precocious puberty, and a Meeting Granted letter was issued on November 6, 2018. The sponsor submitted a briefing package on December 12, 2018.

2.0 DISCUSSION

The sponsor's questions are repeated below in regular text, followed by the FDA response (bolded).

Clinical

Question 1: The clinical study data will be submitted using approved CDISC data sets. Tables, listings and figures shells to be included in the Clinical Study Report are provided in Appendix 2. Is this acceptable to the Agency or are there any additional SAS Tables that the Agency would like to see for the review of the datasets?

FDA Response to Question 1:

For all studies included in the submission, you must submit either ADaM or analysis datasets, and either SDTM or CRF tabulation datasets. We acknowledge that you plan to submit the datasets in CDISC standard format. You must also submit reviewer's guides for all submitted datasets.

Each analysis dataset should include baseline assessments and key demographic variables. The analysis datasets should include all variables needed for conducting all primary, secondary, and sensitivity analyses included in the study report. For endpoints that include imputations, both observed and imputed variables should be included and clearly identified.

Include sufficient detail, such as definitions or descriptions of each variable in the datasets, algorithms for derived variables (including source variable[s] used), and descriptions for the code used in factor variables in the analysis dataset documentation (Define.pdf).

Include the software programs that are used to create the derived datasets for the efficacy endpoints and the software programs that are used for efficacy data analysis.

Label

Question 2: Tolmar plans to develop the Package Insert for the CPP indication based on the clinical trial TOL2581A and the Package Inserts from the ELIGARD and the Lupron Depot-

PED® products. Tolmar will also follow all relevant guidance related to labeling. A draft of the proposed label is provided in Appendix 1.

Does the agency concur this approach is acceptable?

FDA Response to Question 2:

This approach is acceptable, however, final labeling will be a review issue.

We have the following additional comment with respect to the labeling:

Impairment of fertility information is understandably lacking in the current label for treatment of advanced prostate cancer. However, such information is pertinent to an adolescent CPP population and should be included in the drug label for a product with this indication. Therefore, include this information for leuprolide in draft labeling for the CPP indication.

Regulatory

Question 3: In the pre-IND briefing package dated August 28, 2014, Question 12 stated Tolmar's intent to cross-reference NDA 021731 for the nonclinical, CMC and other relevant information to support the new NDA filing for the CPP indication. In the written response (Appendix 6) dated September 29, 2014, the Division agreed that Tolmar could cross-reference information already submitted to NDA 021731.

Thus, Tolmar intends to submit a cross reference authorization letter in the new NDA for the CPP indication to authorize the FDA to reference all of the information already submitted under NDA 021731. Tolmar believes this provides the least burdensome path and allows for ease of review as the FDA has already approved the nonclinical and CMC sections for NDA 021731. These sections would be identical for the CPP indication. An example of the letter is provided in Appendix 5.

Does the Agency confirm that this approach is still acceptable?

FDA Response to Question 3:

Yes, this is acceptable. However, given the long history of NDA 021731, please provide a copy of the current approved specifications for the drug substance and drug product.

Question 4: Tolmar proposes to submit a cross reference authorization letter to the new NDA for any supplements and/or amendments filed to NDA 021731 during the new NDA's review period.

Does the agency concur this approach is acceptable?

FDA Response to Question 4:

Yes, this is acceptable from a CMC perspective. Given the long history of NDA 021731 and for ease of review of the new NDA, please provide specific citations appropriately hyperlinked and be prepared to respond to specific discipline questions during the review.

Question 5: Tolmar proposes to submit any post-approval CMC related supplements for leuprolide acetate for injectable suspension, 45 mg only to NDA 021731 and a cross reference authorization letter to reference NDA 021731 to the CPP application. An example of the letter is provided in Appendix 5.

Does the agency concur this approach is acceptable?

FDA Response to Question 5:

The example reference letters in Appendix 5 are general in nature and may not be sufficient to cross-reference specific topics. Include details for a specific cross-referenced topic to facilitate review of the new NDA. Be specific regarding cross-referenced CMC information that is identical to the approved product, and any modifications that pertain to the new product. Use tables to compare and contrast. Please refer to our response to question 4.

Question 6: Tolmar respectfully requests clarification to the following statement made in the introduction of FDA's written response (Appendix 6) dated September 29, 2014: "The sponsor plans to eventually submit the results of Study TOL2581A as a supplemental New Drug Application (sNDA) to NDA 021731 via the 505(b)(2) regulatory pathway, approved on December 14, 2004." Please clarify; the sNDA referenced in this statement is not a supplemental submission to NDA 021731 but a new NDA for the CPP indication. The new NDA will contain clinical data from Study TOL2581A and cross-reference NDA 021731 for the nonclinical, CMC and other relevant information.

Does the agency concur?

FDA Response to Question 6:

While you could submit a supplement to NDA 021731 for the proposed new indication for CPP, your proposal to submit a new NDA via the 505(b)(2) pathway is acceptable to the Division.

3.0 ADDITIONAL INFORMATION

HUMAN FACTORS COMMENTS

It appears that you plan to use the same device platform used for the Eligard product. However, we are aware that there have been postmarketing issues with Eligard (e.g., administration of diluent, confusion between the two tray labels), which have led to usability problems in the market. Please explain whether you plan to implement mitigations to address those issues and if so:

a. describe what those mitigations are, and
b. whether those will apply to the proposed leuprolide product.

PREA REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Please be advised that under the Food and Drug Administration Safety and Innovation Act (FDASIA), you must submit an Initial Pediatric Study Plan (iPSP) within 60 days of an End-of-Phase-2 (EOP2) meeting. In the absence of an EOP2 meeting, refer to the draft guidance below. The iPSP must contain an outline of the pediatric study or studies that you plan to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach); any request for a deferral, partial waiver, or waiver, if applicable, along with any supporting documentation, and any previously negotiated pediatric plans with other regulatory authorities. The iPSP should be submitted in PDF and Word format. Failure to include an Agreed iPSP with a marketing application could result in a refuse to file action.

For additional guidance on the timing, content, and submission of the iPSP, including an iPSP Template, please refer to the draft guidance for industry, *Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans* at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM360507.pdf. In addition, you may contact the Division of Pediatric and Maternal Health at 301-796-2200 or email Pedsdrugs@fda.hhs.gov. For further guidance on pediatric product development, please refer to: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049867.htm.

PRESCRIBING INFORMATION

In your application, you must submit proposed prescribing information (PI) that conforms to the content and format regulations found at 21 CFR 201.56(a) and (d) and 201.57 including the Pregnancy and Lactation Labeling Rule (PLLR) (for applications submitted on or after June 30, 2015). As you develop your proposed PI, we encourage you to review the labeling review

resources on the *PLR Requirements for Prescribing Information* and *Pregnancy and Lactation Labeling Final Rule* websites, which include:

- The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products.
- The Final Rule (Pregnancy and Lactation Labeling Rule) on the content and format of information related to pregnancy, lactation, and females and males of reproductive potential.
- Regulations and related guidance documents.
- A sample tool illustrating the format for Highlights and Contents, and
- The Selected Requirements for Prescribing Information (SRPI) − a checklist of important format items from labeling regulations and guidances.
- FDA's established pharmacologic class (EPC) text phrases for inclusion in the Highlights Indications and Usage heading.

Pursuant to the PLLR, you should include the following information with your application to support the changes in the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling. The application should include a review and summary of the available published literature regarding the drug's use in pregnant and lactating women and the effects of the drug on male and female fertility (include search parameters and a copy of each reference publication), a cumulative review and summary of relevant cases reported in your pharmacovigilance database (from the time of product development to present), a summary of drug utilization rates amongst females of reproductive potential (e.g., aged 15 to 44 years) calculated cumulatively since initial approval, and an interim report of an ongoing pregnancy registry or a final report on a closed pregnancy registry. If you believe the information is not applicable, provide justification. Otherwise, this information should be located in Module 1. Refer to the draft guidance for industry – *Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products – Content and Format* (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425398.pdf).

Prior to submission of your proposed PI, use the SRPI checklist to ensure conformance with the format items in regulations and guidances.

DISCUSSION OF SAFETY ANALYSIS STRATEGY FOR THE ISS

After initiation of all trials planned for the phase 3 program, you should consider requesting a Type C meeting to gain agreement on the safety analysis strategy for the Integrated Summary of Safety (ISS) and related data requirements. Topics of discussion at this meeting would include pooling strategy (i.e., specific studies to be pooled and analytic methodology intended to manage between-study design differences, if applicable), specific queries including use of specific standardized MedDRA queries (SMQs), and other important analyses intended to support safety. The meeting should be held after you have drafted an analytic plan for the ISS, and prior to programming work for pooled or other safety analyses planned for inclusion in the ISS. This meeting, if held, would

precede the Pre-NDA meeting. Note that this meeting is optional; the issues can instead be addressed at the pre-NDA meeting.

To optimize the output of this meeting, submit the following documents for review as part of the briefing package:

- Description of all trials to be included in the ISS. Please provide a tabular listing of clinical trials including appropriate details.
- ISS statistical analysis plan, including proposed pooling strategy, rationale for inclusion or exclusion of trials from the pooled population(s), and planned analytic strategies to manage differences in trial designs (e.g., in length, randomization ratio imbalances, study populations, etc.).
- For a phase 3 program that includes trial(s) with multiple periods (e.g., double-blind randomized period, long-term extension period, etc.), submit planned criteria for analyses across the program for determination of start / end of trial period (i.e., method of assignment of study events to a specific study period).
- Prioritized list of previously observed and anticipated safety issues to be evaluated, and planned analytic strategy including any SMQs, modifications to specific SMQs, or sponsor-created groupings of Preferred Terms. A rationale supporting any proposed modifications to an SMQ or sponsor-created groupings should be provided.

When requesting this meeting, clearly mark your submission "**DISCUSS SAFETY ANALYSIS STRATEGY FOR THE ISS**" in large font, bolded type at the beginning of the cover letter for the Type C meeting request.

MANUFACTURING FACILITIES

To facilitate our inspectional process, we request that you clearly identify *in a single location*, either on the Form FDA 356h, or an attachment to the form, all manufacturing facilities associated with your application. Include the full corporate name of the facility and address where the manufacturing function is performed, with the FEI number, and specific manufacturing responsibilities for each facility.

Also provide the name and title of an onsite contact person, including their phone number, fax number, and email address. Provide a brief description of the manufacturing operation conducted at each facility, including the type of testing and DMF number (if applicable). Each facility should be ready for GMP inspection at the time of submission.

Consider using a table similar to the one below as an attachment to Form FDA 356h. Indicate under Establishment Information on page 1 of Form FDA 356h that the information is provided in the attachment titled, "Product name, NDA/BLA 012345, Establishment Information for Form 356h."

Site Name	Site Address	Federal Establishment Indicator (FEI) or Registration Number (CFN)	Drug Master File Number (if applicable)	Manufacturing Step(s) or Type of Testing [Establishment function]
1.				
2.				

Corresponding names and titles of onsite contact:

Site Name	Site Address	Onsite Contact (Person, Title)	Phone and Fax number	Email address
1.				
2.				

505(b)(2) REGULATORY PATHWAY

The Division recommends that sponsors considering the submission of an application through the 505(b)(2) pathway consult the Agency's regulations at 21 CFR 314.54, and the draft guidance for industry, *Applications Covered by Section 505(b)(2)* (October 1999), available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm. In addition, FDA has explained the background and applicability of section 505(b)(2) in its October 14, 2003, response to a number of citizen petitions that had challenged the Agency's interpretation of this statutory provision (see Docket FDA-2003-P-0274-0015, available at http://www.regulations.gov).

If you intend to submit a 505(b)(2) application that relies for approval on FDA's finding of safety and/or effectiveness for one or more listed drugs, you must establish that such reliance is scientifically appropriate, and must submit data necessary to support any aspects of the proposed drug product that represent modifications to the listed drug(s). You should establish a "bridge" (e.g., via comparative bioavailability data) between your proposed drug product and each listed drug upon which you propose to rely to demonstrate that such reliance is scientifically justified.

If you intend to rely on literature or other studies for which you have no right of reference but that are necessary for approval, you also must establish that reliance on the studies described in the literature or on the other studies is scientifically appropriate. You should include a copy of such published literature in the 505(b)(2) application and identify any listed drug(s) described in the published literature (e.g. by trade name(s)).

If you intend to rely on the Agency's finding of safety and/or effectiveness for a listed drug(s) or published literature describing a listed drug(s) (which is considered to be reliance on FDA's finding of safety and/or effectiveness for the listed drug(s)), you should identify the listed drug(s) in accordance with the Agency's regulations at 21 CFR 314.54. It should be noted that 21 CFR 314.54 requires identification of the "listed drug for which FDA has made a finding of safety and effectiveness," and thus an applicant may only rely upon a listed drug that was approved in an NDA under section 505(c) of the FD&C Act. The regulatory requirements for a 505(b)(2) application (including, but not limited to, an appropriate patent certification or statement) apply to each listed drug upon which a sponsor relies.

If FDA has approved one or more pharmaceutically equivalent products in one or more NDA(s) before the date of submission of the original 505(b)(2) application, you must identify one such pharmaceutically equivalent product as a listed drug (or an additional listed drug) relied upon (see 21 CFR 314.50(i)(1)(i)(C), 314.54, and 314.125(b)(19); see also 21 CFR 314.101(d)(9)). If you identify a listed drug solely to comply with this regulatory requirement, you must provide an appropriate patent certification or statement for any patents that are listed in the Orange Book for the pharmaceutically equivalent product, but you are not required to establish a "bridge" to justify the scientific appropriateness of reliance on the pharmaceutically equivalent product if it is scientifically unnecessary to support approval.

If you propose to rely on FDA's finding of safety and/or effectiveness for a listed drug that has been discontinued from marketing, the acceptability of this approach will be contingent on FDA's consideration of whether the drug was discontinued for reasons of safety or effectiveness.

We encourage you to identify each section of your proposed 505(b)(2) application that is supported by reliance on FDA's finding of safety and/or effectiveness for a listed drug(s) or on published literature (see table below). In your 505(b)(2) application, we encourage you to clearly identify (for each section of the application, including the labeling): (1) the information for the proposed drug product that is provided by reliance on FDA's finding of safety and/or effectiveness for the listed drug or by reliance on published literature; (2) the "bridge" that supports the scientific appropriateness of such reliance; and (3) the specific name (e.g., proprietary name) of each listed drug named in any published literature on which your marketing application relies for approval. If you are proposing to rely on published literature, include copies of the article(s) in your submission.

In addition to identifying the source of supporting information in your annotated labeling, we encourage you to include in your marketing application a summary of the information that supports the application in a table similar to the one below.

List the information essential to the approval of the proposed drug that is provided by reliance on the FDA's previous finding of safety and effectiveness for a listed drug or by reliance on published literature

Source of information (e.g., published literature, name of listed drug)	Information Provided (e.g., specific sections of the 505(b)(2) application or labeling)
1. Example: Published literature	*Nonclinical toxicology*
2. Example: NDA XXXXXX "TRADENAME"	*Previous finding of effectiveness for indication A*
3. Example: NDA YYYYYY "TRADENAME"	*Previous finding of safety for Carcinogenicity, labeling section B*
4.	

Please be advised that circumstances could change that would render a 505(b)(2) application for this product no longer appropriate. For example, if a pharmaceutically equivalent product were approved before your application is submitted, such that your proposed product would be a "duplicate" of a listed drug and eligible for approval under section 505(j) of the FD&C Act, then it is FDA's policy to refuse to file your application as a 505(b)(2) application (21 CFR 314.101(d)(9)). In such a case, the appropriate submission would be an Abbreviated New Drug Application (ANDA) that cites the duplicate product as the reference listed drug.

OFFICE OF SCIENTIFIC INVESTIGATIONS (OSI) REQUESTS

The Office of Scientific Investigations (OSI) requests that the items described in the draft Guidance for Industry Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions (February 2018) and the associated Bioresearch Monitoring Technical Conformance Guide Containing Technical Specifications be provided to facilitate development of clinical investigator and sponsor/monitor/CRO inspection assignments, and the background packages that are sent with those assignments to the FDA ORA investigators who conduct those inspections. This information is requested for all major trials used to support safety and efficacy in the application (i.e., phase 2/3 pivotal trials). Please note that if the requested items are provided elsewhere in submission in the format described, the Applicant can describe location or provide a link to the requested information.

Please refer to the draft Guidance for Industry Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions (February 2018) and the associated Bioresearch Monitoring Technical Conformance Guide Containing Technical Specifications:

https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/UCM332466.pdf

https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/UCM332468.pdf.

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/

JENNIFER L JOHNSON
01/09/2019 05:39:46 PM