

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**201739Orig1s000**

**ADMINISTRATIVE and CORRESPONDENCE  
DOCUMENTS**

## EXCLUSIVITY SUMMARY

NDA # 201739

SUPPL #

HFD # 570

Trade Name e-cue

Generic Name Epinephrine Auto- Injector

Applicant Name Intelliject Inc.

Approval Date, If Known

### PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES  NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3,SE4, SE5, SE6, SE7, SE8

505(b)(2)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES  NO

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

The application provides for combination product using a new device. The safety and efficacy of the reference listed drug, Epipen has been established; therefore, only bioavailability study is required.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

NA

d) Did the applicant request exclusivity?

YES  NO

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

3 years

e) Has pediatric exclusivity been granted for this Active Moiety?

YES  NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES  NO

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

## **PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES**

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES  NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# 019430 EpiPen/EpiPenJr

NDA# 20800 Twinjet

NDA#

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES  NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)  
IF "YES," GO TO PART III.

**PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS**

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of

summary for that investigation.

YES  NO

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES  NO

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES  NO

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES  NO

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES  NO

If yes, explain:

- (c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

- a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES  NO

Investigation #2 YES  NO

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

- b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES  NO

Investigation #2 YES  NO

If you have answered "yes" for one or more investigation, identify the NDA in which a



Explain:

! Explain:

Investigation #2

!

!

YES

! NO

Explain:

! Explain:

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES

NO

If yes, explain:

=====

Name of person completing form: Angela Ramsey  
Title: Senior Regulatory Project Manager  
Date: July 29, 2011

Name of Office/Division Director signing form: Badrul A. Chowdhury  
Title: Director

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05

-----  
**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ANGELA H RAMSEY  
07/29/2011

BADRUL A CHOWDHURY  
07/29/2011

# ACTION PACKAGE CHECKLIST

## APPLICATION INFORMATION<sup>1</sup>

NDA # 201739 BLA #	NDA Supplement # BLA STN #	If NDA, Efficacy Supplement Type:
Proprietary Name: Auvi-Q Established/Proper Name: Epinephrine Injection USP 1:1000 Dosage Form: Auto-Injector		Applicant: Intelliject Agent for Applicant (if applicable):
RPM: Angela Ramsey		Division: Pulmonary, Allergy, and Rheumatology Products
<p><b>NDA:</b> NDA Application Type: <input type="checkbox"/> 505(b)(1) <input checked="" type="checkbox"/> 505(b)(2) Efficacy Supplement: <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)</p> <p>(A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). Consult page 1 of the 505(b)(2) Assessment or the Appendix to this Action Package Checklist.)</p>		<p><b>505(b)(2) Original NDAs and 505(b)(2) NDA supplements:</b> Listed drug(s) relied upon for approval (include NDA #(s) and drug name(s)):</p> <p>EpiPen</p> <p>Provide a brief explanation of how this product is different from the listed drug.</p> <p>The device is new; therefore, the application was not eligible for submission under 505(j) per OGD.</p> <p>If no listed drug, explain.</p> <p><input type="checkbox"/> This application relies on literature. <input type="checkbox"/> This application relies on a final OTC monograph. <input type="checkbox"/> Other (explain)</p> <p><b><u>Two months prior to each action, review the information in the 505(b)(2) Assessment and submit the draft to CDER OND IO for clearance. Finalize the 505(b)(2) Assessment at the time of the approval action.</u></b></p> <p><b><u>On the day of approval, check the Orange Book again for any new patents or pediatric exclusivity.</u></b></p> <p><input checked="" type="checkbox"/> No changes    <input type="checkbox"/> Updated    Date of check:</p> <p><b>If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.</b></p>
❖ Actions		
<ul style="list-style-type: none"> <li>• Proposed action</li> <li>• User Fee Goal Date is <u>November 7, 2012</u></li> <li>• Previous actions (<i>specify type and date for each action taken</i>)</li> </ul>		<input checked="" type="checkbox"/> AP <input type="checkbox"/> TA <input type="checkbox"/> CR  <input type="checkbox"/> None    TA July 29, 2011

The **Application Information** section is (only) a checklist. The **Contents of Action Package** section (beginning on page 5) lists the documents to be included in the Action Package.

<p>❖ If accelerated approval or approval based on efficacy studies in animals, were promotional materials received?                  Note: Promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see <a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf</a>). If not submitted, explain _____</p>	<p><input type="checkbox"/> Received</p>
<p>❖ Application Characteristics<sup>2</sup></p> <p>Review priority: <input checked="" type="checkbox"/> Standard <input type="checkbox"/> Priority                  Chemical classification (new NDAs only):</p> <p><input type="checkbox"/> Fast Track <input type="checkbox"/> Rx-to-OTC full switch  <input type="checkbox"/> Rolling Review <input type="checkbox"/> Rx-to-OTC partial switch  <input type="checkbox"/> Orphan drug designation <input type="checkbox"/> Direct-to-OTC</p> <p>NDAs: Subpart H <span style="margin-left: 200px;">BLAs: Subpart E</span>  <input type="checkbox"/> Accelerated approval (21 CFR 314.510) <span style="margin-left: 100px;"><input type="checkbox"/> Accelerated approval (21 CFR 601.41)</span>  <input type="checkbox"/> Restricted distribution (21 CFR 314.520) <span style="margin-left: 100px;"><input type="checkbox"/> Restricted distribution (21 CFR 601.42)</span></p> <p>Subpart I <span style="margin-left: 200px;">Subpart H</span>  <input type="checkbox"/> Approval based on animal studies <span style="margin-left: 100px;"><input type="checkbox"/> Approval based on animal studies</span></p> <p><input type="checkbox"/> Submitted in response to a PMR <span style="margin-left: 200px;">REMS: <input type="checkbox"/> MedGuide</span>  <input type="checkbox"/> Submitted in response to a PMC <span style="margin-left: 200px;"><input type="checkbox"/> Communication Plan</span>  <input type="checkbox"/> Submitted in response to a Pediatric Written Request <span style="margin-left: 200px;"><input type="checkbox"/> ETASU</span>  <span style="margin-left: 200px;"><input checked="" type="checkbox"/> REMS not required</span></p> <p>Comments:</p>	
<p>❖ BLAs only: Ensure <i>RMS-BLA Product Information Sheet for TBP</i> and <i>RMS-BLA Facility Information Sheet for TBP</i> have been completed and forwarded to OPI/OBI/DRM (Vicky Carter)</p>	<p><input type="checkbox"/> Yes, dates</p>
<p>❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 (<i>approvals only</i>)</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>❖ Public communications (<i>approvals only</i>)</p>	
<p>• Office of Executive Programs (OEP) liaison has been notified of action</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>• Press Office notified of action (by OEP)</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>• Indicate what types (if any) of information dissemination are anticipated</p>	<p><input checked="" type="checkbox"/> None  <input type="checkbox"/> HHS Press Release  <input type="checkbox"/> FDA Talk Paper  <input type="checkbox"/> CDER Q&amp;As  <input type="checkbox"/> Other</p>

<sup>2</sup> Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA. For example, if the application is a pending BLA supplement, then a new *RMS-BLA Product Information Sheet for TBP* must be completed.

❖ Exclusivity	
<ul style="list-style-type: none"> <li>Is approval of this application blocked by any type of exclusivity?</li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
<ul style="list-style-type: none"> <li>NDA and BLAs: Is there existing orphan drug exclusivity for the "same" drug or biologic for the proposed indication(s)? <i>Refer to 21 CFR 316.3(b)(13) for the definition of "same drug" for an orphan drug (i.e., active moiety). This definition is NOT the same as that used for NDA chemical classification.</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If, yes, NDA/BLA # _____ and date exclusivity expires: _____
<ul style="list-style-type: none"> <li>(b)(2) NDAs only: Is there remaining 5-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # _____ and date exclusivity expires: _____
<ul style="list-style-type: none"> <li>(b)(2) NDAs only: Is there remaining 3-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # _____ and date exclusivity expires: _____
<ul style="list-style-type: none"> <li>(b)(2) NDAs only: Is there remaining 6-month pediatric exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # _____ and date exclusivity expires: _____
<ul style="list-style-type: none"> <li>NDAs only: Is this a single enantiomer that falls under the 10-year approval limitation of 505(u)? <i>(Note that, even if the 10-year approval limitation period has not expired, the application may be tentatively approved if it is otherwise ready for approval.)</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # _____ and date 10-year limitation expires: _____
❖ Patent Information (NDAs only)	
<ul style="list-style-type: none"> <li>Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought. If the drug is an old antibiotic, skip the Patent Certification questions.</li> </ul>	<input checked="" type="checkbox"/> Verified <input type="checkbox"/> Not applicable because drug is an old antibiotic.
<ul style="list-style-type: none"> <li>Patent Certification [505(b)(2) applications]: Verify that a certification was submitted for each patent for the listed drug(s) in the Orange Book and identify the type of certification submitted for each patent.</li> </ul>	21 CFR 314.50(i)(1)(i)(A) <input checked="" type="checkbox"/> Verified  21 CFR 314.50(i)(1) <input type="checkbox"/> (ii) <input type="checkbox"/> (iii)
<ul style="list-style-type: none"> <li>[505(b)(2) applications] If the application includes a <b>paragraph III</b> certification, it cannot be approved until the date that the patent to which the certification pertains expires (but may be tentatively approved if it is otherwise ready for approval).</li> </ul>	<input checked="" type="checkbox"/> No paragraph III certification Date patent will expire _____
<ul style="list-style-type: none"> <li>[505(b)(2) applications] For <b>each paragraph IV</b> certification, verify that the applicant notified the NDA holder and patent owner(s) of its certification that the patent(s) is invalid, unenforceable, or will not be infringed (review documentation of notification by applicant and documentation of receipt of notice by patent owner and NDA holder). <i>(If the application does not include any paragraph IV certifications, mark "N/A" and skip to the next section below (Summary Reviews)).</i></li> </ul>	<input type="checkbox"/> N/A (no paragraph IV certification) <input checked="" type="checkbox"/> Verified

- [505(b)(2) applications] For **each paragraph IV** certification, based on the questions below, determine whether a 30-month stay of approval is in effect due to patent infringement litigation.

Answer the following questions for **each** paragraph IV certification:

- (1) Have 45 days passed since the patent owner's receipt of the applicant's notice of certification?

Yes  No

(Note: The date that the patent owner received the applicant's notice of certification can be determined by checking the application. The applicant is required to amend its 505(b)(2) application to include documentation of this date (e.g., copy of return receipt or letter from recipient acknowledging its receipt of the notice) (see 21 CFR 314.52(e)).

*If "Yes," skip to question (4) below. If "No," continue with question (2).*

- (2) Has the patent owner (or NDA holder, if it is an exclusive patent licensee) submitted a written waiver of its right to file a legal action for patent infringement after receiving the applicant's notice of certification, as provided for by 21 CFR 314.107(f)(3)?

Yes  No

*If "Yes," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip the rest of the patent questions.*

*If "No," continue with question (3).*

- (3) Has the patent owner, its representative, or the exclusive patent licensee filed a lawsuit for patent infringement against the applicant?

Yes  No

(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)).

*If "No," the patent owner (or NDA holder, if it is an exclusive patent licensee) has until the expiration of the 45-day period described in question (1) to waive its right to bring a patent infringement action or to bring such an action. After the 45-day period expires, continue with question (4) below.*

- (4) Did the patent owner (or NDA holder, if it is an exclusive patent licensee) submit a written waiver of its right to file a legal action for patent infringement within the 45-day period described in question (1), as provided for by 21 CFR 314.107(f)(3)?

Yes  No

*If "Yes," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).*

*If "No," continue with question (5).*

<p>(5) Did the patent owner, its representative, or the exclusive patent licensee bring suit against the (b)(2) applicant for patent infringement within 45 days of the patent owner's receipt of the applicant's notice of certification?</p> <p>(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)). If no written notice appears in the NDA file, confirm with the applicant whether a lawsuit was commenced within the 45-day period).</p> <p><i>If "No," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).</i></p> <p><i>If "Yes," a stay of approval may be in effect. To determine if a 30-month stay is in effect, consult with the OND ADRA and attach a summary of the response.</i></p>	<p><input type="checkbox"/> Yes    <input checked="" type="checkbox"/> No</p>
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**CONTENTS OF ACTION PACKAGE**

<p>Copy of this Action Package Checklist<sup>3</sup></p>	<p>Yes</p>
<p align="center"><b>Officer/Employee List</b></p>	
<p>❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list (<i>approvals only</i>)</p>	<p><input checked="" type="checkbox"/> Included</p>
<p>Documentation of consent/non-consent by officers/employees</p>	<p><input checked="" type="checkbox"/> Included</p>
<p align="center"><b>Action Letters</b></p>	
<p>❖ Copies of all action letters (<i>including approval letter with final labeling</i>)</p>	<p>Action(s) and date(s) AP: August x, 2012; TA: July 29, 2011</p>
<p align="center"><b>Labeling</b></p>	
<p>❖ Package Insert (<i>write submission/communication date at upper right of first page of PI</i>)</p>	
<ul style="list-style-type: none"> <li>• Most recent draft labeling. If it is division-proposed labeling, it should be in track-changes format.</li> </ul>	<p>8/6/12; 8/3/12; 7/5/12; 5/7/12; 7/22/11; 7/20/11; 7/15/11, 6/20/11</p>
<ul style="list-style-type: none"> <li>• Original applicant-proposed labeling</li> </ul>	<p>9/29/10</p>
<ul style="list-style-type: none"> <li>• Example of class labeling, if applicable</li> </ul>	<p>NA</p>

<sup>3</sup> Fill in blanks with dates of reviews, letters, etc.

<ul style="list-style-type: none"> <li>❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling (<i>write submission/communication date at upper right of first page of each piece</i>)</li> </ul>	<input type="checkbox"/> Medication Guide <input type="checkbox"/> Patient Package Insert <input checked="" type="checkbox"/> Instructions for Use <input checked="" type="checkbox"/> Device Labeling <input type="checkbox"/> None
<ul style="list-style-type: none"> <li>• Most-recent draft labeling. If it is division-proposed labeling, it should be in track-changes format.</li> </ul>	8/3/12; 7/5/12; 5/7/12; 7/22/11; 7/20/11; 7/15/11, 6/20/11
<ul style="list-style-type: none"> <li>• Original applicant-proposed labeling</li> </ul>	9/29/10
<ul style="list-style-type: none"> <li>• Example of class labeling, if applicable</li> </ul>	NA
<ul style="list-style-type: none"> <li>❖ Labels (<b>full color</b> carton and immediate-container labels) (<i>write submission/communication date on upper right of first page of each submission</i>)</li> </ul>	
<ul style="list-style-type: none"> <li>• Most-recent draft labeling</li> </ul>	8/3/12; 7/5/12; 5/7/12; 7/1/11
<ul style="list-style-type: none"> <li>❖ Proprietary Name                     <ul style="list-style-type: none"> <li>• Acceptability/non-acceptability letter(s) (<i>indicate date(s)</i>)</li> <li>• Review(s) (<i>indicate date(s)</i>)</li> </ul> </li> </ul>	7/31/12- acceptable 6/29/12- unacceptable 7/20/11- acceptable 12/28/11- unacceptable
<ul style="list-style-type: none"> <li>❖ Labeling reviews (<i>indicate dates of reviews and meetings</i>)</li> </ul>	<input checked="" type="checkbox"/> RPM 7/19/11 <input checked="" type="checkbox"/> DMEPA 7/31/12; 6/7/20/11; 4/28/11 <input checked="" type="checkbox"/> DRISK 6/6/11 <input checked="" type="checkbox"/> DDMAC 6/17/11 <input type="checkbox"/> CSS <input checked="" type="checkbox"/> Other reviews 3/21/11- REMS review
<b>Administrative / Regulatory Documents</b>	
<ul style="list-style-type: none"> <li>❖ Administrative Reviews (<i>e.g., RPM Filing Review<sup>4</sup>/Memo of Filing Meeting</i>) (<i>indicate date of each review</i>)</li> </ul>	11/19/10; 6/7/11
<ul style="list-style-type: none"> <li>❖ All NDA (b)(2) Actions: Date each action cleared by (b)(2) Clearance Cmte</li> <li>❖ NDA (b)(2) Approvals Only: 505(b)(2) Assessment (<i>indicate date</i>)</li> </ul>	<input type="checkbox"/> Not a (b)(2) 7/19/11 <input type="checkbox"/> Not a (b)(2) 7/19/11
<ul style="list-style-type: none"> <li>❖ NDAs only: Exclusivity Summary (<i>signed by Division Director</i>)</li> </ul>	<input checked="" type="checkbox"/> Included
<ul style="list-style-type: none"> <li>❖ Application Integrity Policy (AIP) Status and Related Documents  <a href="http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm">http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm</a> </li> </ul>	
<ul style="list-style-type: none"> <li>• Applicant is on the AIP</li> </ul>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> <li>• This application is on the AIP                     <ul style="list-style-type: none"> <li>○ If yes, Center Director's Exception for Review memo (<i>indicate date</i>)</li> <li>○ If yes, OC clearance for approval (<i>indicate date of clearance communication</i>)</li> </ul> </li> </ul>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  <input type="checkbox"/> Not an AP action
<ul style="list-style-type: none"> <li>❖ Pediatrics (<i>approvals only</i>)                     <ul style="list-style-type: none"> <li>• Date reviewed by PeRC _____                              If PeRC review not necessary, explain: <u>Proposed product does not contain any new active ingredients, indications, dosage forms, dosing regimens, or new routes of administration</u></li> <li>• Pediatric Page/Record (<i>approvals only, must be reviewed by PERC before finalized</i>)</li> </ul> </li> </ul>	<input type="checkbox"/> Included

<sup>4</sup> Filing reviews for scientific disciplines should be filed behind the respective discipline tab.  
 Version: 8/25/10

❖ Debarment certification (original applications only): verified that qualifying language was not used in certification and that certifications from foreign applicants are cosigned by U.S. agent ( <i>include certification</i> )	<input checked="" type="checkbox"/> Verified, statement is acceptable
❖ Outgoing communications ( <i>letters (except action letters), emails, faxes, telecons</i> )	7/22/11; 7/15/11; 6/20/11; 5/20/11; 3/15/11; 3/8/11; 2/28/11; 2/24/11; 1/25/11
❖ Internal memoranda, telecons, etc.	12/23/10; 2/2/11; 3/15/11
❖ Minutes of Meetings	
• Regulatory Briefing ( <i>indicate date of mtg</i> )	<input checked="" type="checkbox"/> No mtg
• If not the first review cycle, any end-of-review meeting ( <i>indicate date of mtg</i> )	<input checked="" type="checkbox"/> N/A or no mtg
• Pre-NDA/BLA meeting ( <i>indicate date of mtg</i> )	<input type="checkbox"/> No mtg 10/26/09
• EOP2 meeting ( <i>indicate date of mtg</i> )	<input type="checkbox"/> No mtg
• Other milestone meetings (e.g., EOP2a, CMC pilots) ( <i>indicate dates of mtgs</i> )	
❖ Advisory Committee Meeting(s)	<input checked="" type="checkbox"/> No AC meeting
• Date(s) of Meeting(s)	
• 48-hour alert or minutes, if available ( <i>do not include transcript</i> )	
<b>Decisional and Summary Memos</b>	
❖ Office Director Decisional Memo ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> None
Division Director Summary Review ( <i>indicate date for each review</i> )	<input type="checkbox"/> None 7/29/11
Cross-Discipline Team Leader Review ( <i>indicate date for each review</i> )	<input type="checkbox"/> None 8/6/12; 6/19/12; 7/8/11
PMR/PMC Development Templates ( <i>indicate total number</i> )	<input checked="" type="checkbox"/> None
<b>Clinical Information<sup>5</sup></b>	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) ( <i>indicate date for each review</i> )	6/19/12; See CDTL Review 7/8/11
• Clinical review(s) ( <i>indicate date for each review</i> )	6/24/11; 11/9/10
• Social scientist review(s) (if OTC drug) ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here <input type="checkbox"/> and include a review/memo explaining why not ( <i>indicate date of review/memo</i> )	See clinical review dated 6/24/11
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers ( <i>indicate date of each review</i> )	<input checked="" type="checkbox"/> None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation ( <i>indicate date of each review</i> )	<input checked="" type="checkbox"/> Not applicable
❖ Risk Management	
• REMS Documents and Supporting Statement ( <i>indicate date(s) of submission(s)</i> )	
• REMS Memo(s) and letter(s) ( <i>indicate date(s)</i> )	
• Risk management review(s) and recommendations (including those by OSE and CSS) ( <i>indicate date of each review and indicate location/date if incorporated into another review</i> )	<input type="checkbox"/> None March 21, 2011

<sup>5</sup> Filing reviews should be filed with the discipline reviews.

❖ DSI Clinical Inspection Review Summary(ies) (include copies of DSI letters to investigators)	<input checked="" type="checkbox"/> None requested
<b>Clinical Microbiology</b> <input checked="" type="checkbox"/> None	
❖ Clinical Microbiology Team Leader Review(s) (indicate date for each review)	<input type="checkbox"/> None
Clinical Microbiology Review(s) (indicate date for each review)	<input type="checkbox"/> None
<b>Biostatistics</b> <input type="checkbox"/> None	
❖ Statistical Division Director Review(s) (indicate date for each review)	<input type="checkbox"/> None
Statistical Team Leader Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
Statistical Review(s) (indicate date for each review)	<input type="checkbox"/> None 3/24/11
<b>Clinical Pharmacology</b> <input type="checkbox"/> None	
❖ Clinical Pharmacology Division Director Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
Clinical Pharmacology Team Leader Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
Clinical Pharmacology review(s) (indicate date for each review)	<input type="checkbox"/> None 6/24/11; 11/22/10
❖ DSI Clinical Pharmacology Inspection Review Summary (include copies of DSI letters)	<input type="checkbox"/> None 4/6/11
<b>Nonclinical</b> <input type="checkbox"/> None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
• Supervisory Review(s) (indicate date for each review)	<input type="checkbox"/> None 6/24/11
• Pharm/tox review(s), including referenced IND reviews (indicate date for each review)	<input type="checkbox"/> None 6/22/11; 11/4/10
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer (indicate date for each review)	<input checked="" type="checkbox"/> None
❖ Statistical review(s) of carcinogenicity studies (indicate date for each review)	<input checked="" type="checkbox"/> No carc
❖ ECAC/CAC report/memo of meeting	<input checked="" type="checkbox"/> None Included in P/T review, page
❖ DSI Nonclinical Inspection Review Summary (include copies of DSI letters)	<input checked="" type="checkbox"/> None requested
<b>Product Quality</b> <input type="checkbox"/> None	
❖ Product Quality Discipline Reviews	
• ONDQA/OBP Division Director Review(s) (indicate date for each review)	<input type="checkbox"/> None
• Branch Chief/Team Leader Review(s) (indicate date for each review)	<input type="checkbox"/> None 7/1/11
• Product quality review(s) including ONDQA biopharmaceutics reviews (indicate date for each review)	<input type="checkbox"/> None 5/27/11; 6/24/11; 11/16/10
❖ Microbiology Reviews	<input type="checkbox"/> Not needed 5/13/11
<input checked="" type="checkbox"/> NDAs: Microbiology reviews (sterility & pyrogenicity) (OPS/NDMS) (indicate date of each review)	
<input type="checkbox"/> BLAs: Sterility assurance, microbiology, facilities reviews (DMPQ/MAPCB/BMT) (indicate date of each review)	
❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer (indicate date of each review)	<input type="checkbox"/> None OC 12/22/10; 4/11/11 CDRH 3/1/11; 5/19/11

❖ Environmental Assessment (check one) (original and supplemental applications)	
<input checked="" type="checkbox"/> Categorical Exclusion ( <i>indicate review date</i> )( <i>all original applications and all efficacy supplements that could increase the patient population</i> )	See Quality review dated 6/24/11
<input type="checkbox"/> Review & FONSI ( <i>indicate date of review</i> )	
<input type="checkbox"/> Review & Environmental Impact Statement ( <i>indicate date of each review</i> )	
❖ Facilities Review/Inspection	
<input type="checkbox"/> NDAs: Facilities inspections (include EER printout) ( <i>date completed must be within 2 years of action date</i> ) ( <i>only original NDAs and supplements that include a new facility or a change that affects the manufacturing sites<sup>6</sup></i> )	Date completed: <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation <input type="checkbox"/> Not applicable
<input type="checkbox"/> BLAs: TB-EER ( <i>date of most recent TB-EER must be within 30 days of action date</i> ) ( <i>original and supplemental BLAs</i> )	Date completed: <input type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation
❖ NDAs: Methods Validation ( <i>check box only, do not include documents</i> )	<input type="checkbox"/> Completed <input type="checkbox"/> Requested <input type="checkbox"/> Not yet requested <input checked="" type="checkbox"/> Not needed (per review)

<sup>6</sup> i.e., a new facility or a change in the facility, or a change in the manufacturing process in a way that impacts the Quality Management Systems of the facility.

## Appendix to Action Package Checklist

An NDA or NDA supplemental application is likely to be a 505(b)(2) application if:

- (1) It relies on published literature to meet any of the approval requirements, and the applicant does not have a written right of reference to the underlying data. If published literature is cited in the NDA but is not necessary for approval, the inclusion of such literature will not, in itself, make the application a 505(b)(2) application.
- (2) **Or** it relies for approval on the Agency's previous findings of safety and efficacy for a listed drug product and the applicant does not own or have right to reference the data supporting that approval.
- (3) **Or** it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)

Types of products for which 505(b)(2) applications are likely to be submitted include: fixed-dose combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations); OTC monograph deviations (see 21 CFR 330.11); new dosage forms; new indications; and, new salts.

An efficacy supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2).

An efficacy supplement is a 505(b)(1) supplement if the supplement contains all of the information needed to support the approval of the change proposed in the supplement. For example, if the supplemental application is for a new indication, the supplement is a 505(b)(1) if:

- (1) The applicant has conducted its own studies to support the new indication (or otherwise owns or has right of reference to the data/studies).
- (2) **And** no additional information beyond what is included in the supplement or was embodied in the finding of safety and effectiveness for the original application or previously approved supplements is needed to support the change. For example, this would likely be the case with respect to safety considerations if the dose(s) was/were the same as (or lower than) the original application.
- (3) **And** all other "criteria" are met (e.g., the applicant owns or has right of reference to the data relied upon for approval of the supplement, the application does not rely for approval on published literature based on data to which the applicant does not have a right of reference).

An efficacy supplement is a 505(b)(2) supplement if:

- (1) Approval of the change proposed in the supplemental application would require data beyond that needed to support our previous finding of safety and efficacy in the approval of the original application (or earlier supplement), and the applicant has not conducted all of its own studies for approval of the change, or obtained a right to reference studies it does not own. For example, if the change were for a new indication AND a higher dose, we would likely require clinical efficacy data and preclinical safety data to approve the higher dose. If the applicant provided the effectiveness data, but had to rely on a different listed drug, or a new aspect of a previously cited listed drug, to support the safety of the new dose, the supplement would be a 505(b)(2).
- (2) **Or** the applicant relies for approval of the supplement on published literature that is based on data that the applicant does not own or have a right to reference. If published literature is cited in the supplement but is not necessary for approval, the inclusion of such literature will not, in itself, make the supplement a 505(b)(2) supplement.
- (3) **Or** the applicant is relying upon any data they do not own or to which they do not have right of reference.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, consult with your ODE's ADRA.



NDA 201739

**PROPRIETARY NAME REQUEST  
CONDITIONALLY ACCEPTABLE**

Intelliject, Inc.  
111 Virginia Street  
Suite 405  
Richmond, VA 23219

ATTENTION: Ronald D. Gunn  
Vice President

Dear Mr. Gunn:

Please refer to your New Drug Application (NDA) dated September 29, 2010, received September 29, 2010, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Epinephrine Injection, 0.15 mg/0.15 mL and 0.3 mg/0.3 mL.

We also refer to your July 3, 2012, correspondence, received July 3, 2012, requesting review of your proposed proprietary name, Auvi-Q. We have completed our review of the proposed proprietary name, Auvi-Q and have concluded that it is acceptable.

If **any** of the proposed product characteristics as stated in your July 3, 2012, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Nichelle Rashid, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-3904. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager.

Sincerely,

*{See appended electronic signature page}*

Kellie Taylor, PharmD, MPH  
Deputy Director  
Division of Medication Error Prevention and Analysis  
Office of Medication Error Prevention and Risk Management  
Office of Surveillance and Epidemiology  
Center for Drug Evaluation and Research

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/s/  
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KELLIE A TAYLOR  
07/31/2012



NDA 201739

**ACKNOWLEDGE –  
CLASS 2 RESPONSE**

Intelliject Inc.  
111 Virginia Street, Suite 405  
Richmond, VA 23219

Attention: Ronald Gunn  
Vice President

Dear Mr Gunn:

We acknowledge receipt on May 7, 2012, of your May 7, 2012, resubmission of your new drug application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for e-cue (epinephrine auto-injector).

We consider this a complete, class 2 response to our July 29, 2011, action letter. Therefore, the user fee goal date is November 7, 2012.

If you have any questions, call Angela Ramsey, Senior Program Management Officer, at (301) 796-2284.

Sincerely,

*{See appended electronic signature page}*

Sandy Barnes  
Chief Project Management Staff  
Division of Pulmonary, Allergy, and  
Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/  
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ANGELA H RAMSEY

05/15/2012

AR for SB



NDA 201739

**INFORMATION REQUEST**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Intelliject, Inc.  
111 Virginia Street, Suite 405  
Richmond, VA 23219

Attention: Ronald Gunn  
Vice President, Drug Development & Regulatory Affairs

Dear Mr. Dunn:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for epinephrine Auto-Injector.

FDA investigators have identified significant violations to the bioavailability and bioequivalence requirements of Title 21, Code of Federal Regulation, Part 320 in bioanalytical studies conducted by Cetero Research in Houston, Texas (Cetero).<sup>1</sup> The pervasiveness and egregious nature of the violative practices by Cetero has led FDA to have significant concerns that the bioanalytical data generated at Cetero from April 1, 2005 to June 15, 2010, as part of studies submitted to FDA in New Drug Applications (NDA) and Supplemental New Drug Applications (sNDA) are unreliable. FDA has reached this conclusion for three reasons: (1) the widespread falsification of dates and times in laboratory records for subject sample extractions, (2) the apparent manipulation of equilibration or “prep” run samples to meet pre-determined acceptance criteria, and (3) lack of documentation regarding equilibration or “prep” runs that prevented Cetero and the Agency from determining the extent and impact of these violations.

Serious questions remain about the validity of any data generated in studies by Cetero Research in Houston, Texas during this time period. In view of these findings, FDA is informing holders of approved and pending NDAs of these issues.

The impact of the data from these studies (which may include bioequivalence, bioavailability, drug-drug interaction, specific population, and others) cannot be assessed without knowing the details regarding the study and how the data in question were considered in the overall development and approval of your drug product. At this time, the Office of New Drugs is

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<sup>1</sup> These violations include studies conducted by Bioassay Laboratories and BA Research International specific to the Houston, Texas facility.

searching available documentation to determine which NDAs are impacted by the above findings.

To further expedite this process, we ask that you inform us if you have submitted any studies conducted by Cetero Research in Houston, Texas during the time period of concern (April 1, 2005 to June 15, 2010). Please submit information on each of the studies, including supplement number (if appropriate), study name/protocol number, and date of submission. With respect to those studies, you will need to do one of the following: (a) re-assay samples if available and supported by stability data, (b) repeat the studies, or (c) provide a rationale if you feel that no further action is warranted.

**Please respond to this query within 30 days from the date of this letter.**

This information should be submitted as correspondence to your NDA. In addition, please provide a desk copy to:

Office of New Drugs  
Center for Drug Evaluation and Research  
10903 New Hampshire Avenue  
Bldg. 22, Room 6300  
Silver Spring, MD 20993-0002

If you have any questions, call Christine Chung, Regulatory Project Manager, at (301) 796-3420.

Sincerely,

*{See appended electronic signature page}*

Sandy Barnes  
Chief, Project Management Staff  
Division of Pulmonary, Allergy, and Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/  
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SANDRA L BARNES  
09/15/2011



NDA 201739

**PROPRIETARY NAME REQUEST  
CONDITIONALLY ACCEPTABLE**

Intelliject, Inc.  
c/o: RRD International, LLC.  
7361 Calhoun Place  
Suite 510  
Rockville, Maryland 20855

ATTENTION: Joy Vander Wal, RN, BSN  
Senior Director, Regulatory Affairs

Dear Ms. Vander Wal:

Please refer to your New Drug Application (NDA) dated September 29, 2010, received September 29, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epinephrine Injection, 0.15 mg/0.15 mL and 0.3 mg/0.3 mL.

We also refer to your April 28, 2011, correspondence, received April 28, 2011, requesting review of your proposed proprietary name, e-cue/E-cue. We have completed our review of the proposed proprietary name, e-cue/E-cue and have concluded that it is acceptable.

If **any** of the proposed product characteristics as stated in your April 28, 2011, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Nichelle Rashid, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-3904. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Angela Ramsey at (301) 796-2284.

Sincerely,

*{See appended electronic signature page}*

Carol Holquist, RPh  
Director  
Division of Medication Error Prevention and Analysis  
Office of Medication Error Prevention and Risk  
Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)

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/s/  
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KELLIE A TAYLOR on behalf of CAROL A HOLQUIST  
07/22/2011



**Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation II**

**Memorandum of Facsimile Correspondence**

Date: July 22, 2011

To: Joy K. Van der Wal, RN, BSN  
Sr. Director, Regulatory Affairs

Company: Intelliject, Inc. c/o RRD International LLC

Fax: 301-762-2633

Phone: 301-762-6100 ext 119

From: Angela Ramsey, RN, MSN  
Senior Regulatory Management Officer  
Division of Pulmonary and Allergy Products

Subject: NDA 201739  
Re: FDA Request for Labeling Revisions #3

# of Pages:

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If you are not the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you received this document in error, please immediately notify us by telephone at (301) 796-2300 and return it to us at FDA, 10903 New Hampshire Ave, Building 22, DPAP, Silver Spring, MD 20993.

Thank you.

**NDA 201739**  
**Epinephrine Injection**  
**Intelliject, Inc.**

Your submission dated July 20, 2011, is under review, and we have a request for labeling revisions. The FDA-proposed insertions are underlined and deletions are in strike-out. These comments are not all-inclusive and we may have additional comments and/or requests as we continue our review of the label.

The following comment is in reference to the package insert:

- Replace “XX” with “e-cue®.” When at the start of a new sentence, capitalize the letter “E” to preserve sentence structure and minimize reading confusion.

The following comment is in reference to the patient instruction leaflet and trainer instruction leaflet:

- Replace “TRADENAME” with “e-cue®.”

Submit revised labeling incorporating changes shown in the attached marked up label for the Package Insert (PI), the Instructions for Use (IFU), and the Trainer Instructions for use. Submit a clean copy and a tracked change version of the labeling by COB, Monday, July 25, 2011, to the NDA. In addition, please forward a courtesy copy to Angela Ramsey ([angela.ramsey@fda.hhs.gov](mailto:angela.ramsey@fda.hhs.gov)) via email.

If there are any questions, contact Angela Ramsey, Senior Regulatory Management Officer, at 301-796-2284.

Sincerely,

*{See appended electronic signature page}*

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Angela Ramsey, RN, MSN,  
Senior Regulatory Project Management Officer  
Division of Pulmonary, Allergy, and Rheumatology  
Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: FDA Labeling for PI, IFU, and Trainer IFU

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

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/s/  
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ANGELA H RAMSEY  
07/22/2011



**Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation II**

**Memorandum of Facsimile Correspondence**

Date: July 15, 2011

To: Joy K. Van der Wal, RN, BSN  
Sr. Director, Regulatory Affairs

Company: Intelliject, Inc. c/o RRD International LLC

Fax: 301-762-2633

Phone: 301-762-6100 ext 119

From: Philantha Bowen, MPH, RN  
Senior Regulatory Management Officer  
Division of Pulmonary and Allergy Products

Subject: NDA 201739  
Re: FDA Request for Labeling Revisions #2

# of Pages including cover: 31

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Thank you.

**NDA 201739**  
**Epinephrine Injection**  
**Intelliject, Inc.**

Your submission dated July 1, 2011, NDA 201739 is under review, and we have a request for labeling revisions. The FDA-proposed insertions are underlined and deletions are in strike-out. These comments are not all-inclusive and we may have additional comments and/or requests as we continue our review of the label.

Submit revised labeling incorporating changes shown in the attached marked up label for the Package Insert (PI), the Instructions for Use (IFU), and the Trainer Instructions for use. Submit a clean copy and a tracked change version of the labeling by 10 AM, Wednesday, July 20, 2011, to the NDA. In addition, please forward a courtesy copy to Angela Ramsey ([angela.ramsey@fda.hhs.gov](mailto:angela.ramsey@fda.hhs.gov)) via email.

If there are any questions, contact Angela Ramsey, Senior Regulatory Management Officer, at 301-796-2284.

Sincerely,

*{See appended electronic signature page}*

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Angela Ramsey, MSN, RN  
Senior Regulatory Project Management Officer  
Division of Pulmonary, Allergy, and Rheumatology  
Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: FDA Labeling for PI, IFU, and Trainer IFU

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/s/  
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PHILANTHA M BOWEN

07/15/2011

Acting on behalf of Angela Ramsey



Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation II

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**FACSIMILE TRANSMITTAL SHEET**

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Date: June 20, 2011

<b>To:</b> Joy Vanderwal Senior Director, Regulatory Affairs	<b>From:</b> Angela Ramsey Senior Regulatory Project Manager
<b>Company:</b> Intelliject	Division of Pulmonary, Allergy, and Rheumatology Drug Products
<b>Fax number:</b> 804-545-6219	<b>Fax number:</b> 301-796-9728
<b>Phone number:</b> 804-545-6376	<b>Phone number:</b> 301-796-2284

**Subject:** Division labeling recommendations IR#1

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**Total no. of pages including cover:** 43

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**Comments:**

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**Document to be mailed:**                      YES                      XNO

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If you are not the addressee, or a person authorized to deliver this document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone at (301) 827-1050. Thank you.

NDA 201739  
Epinephrine EAI

In your NDA dated, September 29, 2010, and your amendments dated, February 1, April 1, April 19, and June 7, 2011, we have the following request for labeling revisions. The FDA proposed insertions are underlined and deletions are in strike-out. These comments are not all-inclusive, and we may have additional comments and/or requests as we continue our review of the labels.

Submit revised labeling incorporating the recommended changes shown in the attached marked up Package Insert, Patient Package Information, and trainer Instructions for Use by July 5, 2011. Submit a clean copy and a track changed version of the labels officially to the NDA. In addition, please forward a courtesy copy to me via email.

The following comment pertains to the proposed carton and container labeling submitted on June 7, 2011.

- Remove the audio graphic next to the tradename.

If you have any questions, you may contact me at 301-796-2284.

Drafted by: Ramsey/June 20, 2011

Initialed by: Barnes/June 20, 2011; PB/June 20, 2011; SL/June 20, 2011

Finalized: Ramsey/June 20, 2011

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

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/s/  
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ANGELA H RAMSEY  
06/20/2011



Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation II

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**FACSIMILE TRANSMITTAL SHEET**

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**Date:** May 20, 2011

<b>To:</b> Joy Vanderwal Senior Director, Regulatory Affairs	<b>From:</b> Angela Ramsey Senior Regulatory Project Manager
<b>Company:</b> Intelliject Inc.	Division of Pulmonary, Allergy, and Rheumatology Drug Products
<b>Fax number:</b> 804-545-6219	<b>Fax number:</b> 301-796-9728
<b>Phone number:</b> 804-545-6376	<b>Phone number:</b> 301-796-2284

**Subject:** NDA 201739 Proposed EAI device script

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**Total no. of pages including cover:** 4

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**Comments:** Please acknowledge receipt

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**Document to be mailed:** YES XNO

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NDA 201,739

We are currently reviewing your submissions dated, September 29, and November 4, 2010, and February 1, 2011, and we have the following comments regarding your carton label and container labeling:

**A. General Comments**

1. Based on postmarketing experience we recommend that the Trainer not be packaged in the same carton as the active device. Patients may potentially use an inactive device during an actual emergency. Conversely, patients may get confused while practicing and accidentally inject themselves or someone else with an active device.
2. We note that any statements on the sides of the Outer Case Label and the Device Label will most likely be covered by the patient or caregiver's hand rendering them useless to the patient and thus, should be relocated to an area of the device visually accessible to the patient.
3. Increase the font size of the middle set of digits in the NDC number (e.g., xxxx-XXXX-xx). These digits are used by pharmacists to ensure that the correct product is dispensed.
4. Revise all container labels and carton labeling (including the written instructions on the front panels of the Trainer and active devices) to reflect the changes in voice script that the Applicant agreed to in the correspondence dated March 21, 2011. See Appendices G and H for revised voice scripts.
5. The font color used to express both product strengths is white, thus the two active devices, although different in strength, look similar when compared side-by-side. Ensure the product strengths are well differentiated from one another. The expression of strength should be highlighted by using boxing, shading or some other means and if color is used, it should be different for each strength.
6. Incorrect product selection errors may occur because both active devices utilize the same overall color scheme (red-blue-green versus blue-red-green) on the labels and labeling. The use of different color schemes will improve the differentiation between the two products and decrease the likelihood of wrong strength selection errors.

**B. Outer Case Label (0.15 mg, 0.3 mg, and Trainer)**

1. The triangle symbol at the top of the Outer Case Label may not be understood by patients and caregivers to mean that the device should be pulled out of the case. Please revise so that the statement is more explicit so it is clear how the device separates from its case. One example would be to use the word "pull" instead of (b) (4) as in "pull device from this case", or make the triangle appear more as an arrow symbol.

### **C. Device, Outer Case Label, and Carton Labeling (0.15 mg and 0.3 mg)**

1. Increase the prominence of the established name (epinephrine injection, USP) to be in accordance with 21 CFR 201.10 (g)(2), which takes into consideration not just size of the established name but all pertinent factors, including typography, layout, contrast, and other printing features.
2. Delete the duplicate strength that appears above the proprietary name (in a small box) and increase the prominence of the product strength which follows the established name.
3. Revise the current statement “For single-use injection” to read as follows: “For single-use injection. Refill prescription after use”.

### **D. Device Label, Outer Case Label, and Carton Labeling (Trainer)**

1. Delete the proprietary name (b)(4) and replace with “Trainer for (b)(4)”. Note that the proprietary name (b)(4) should appear in a smaller font than the word “Trainer” to decrease the likelihood that the trainer is not mistaken for the active device. Furthermore, the proprietary name should not be used as a stand alone statement on the Trainer labels and labeling; it should always appear as “Trainer for (b)(4)” and be accompanied by the statement “Contains no active drug or needle”.
2. Revise the text color and background color utilized for the Trainer. Grey text on black background may be hard to read, for example, the word “Front” on the bottom of the outer case label. Additionally, black text on grey background, such as the statement “Auto-Injector Trainer” on the side panel of the outer case label, appears difficult to read.

### **E. Carton Labeling (Trainer)**

1. Revise the Trainer carton colors to match the colors of the Trainer device. Currently the Trainer carton color scheme is similar to the carton color scheme utilized for (b)(4) 0.15 mg, thus creating potential confusion between the Trainer and the active device.

### **F. Physician Sample Outer Case Label and Carton labeling**

1. On the principal display panel include the statement “Physician Sample - Not for Sale”.

If you have any additional questions regarding the NDA application, you may contact Mrs. Angela Ramsey, Senior Regulatory Management Officer, at 301-796-2284.

Drafted by: AR/May 20 11, 2011;  
Initialed by: CH for SB/May 20, 2011; YW/May 20, 2011; PP/May 20, 2011  
Finalized: AR/May 20, 2011

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/s/  
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ANGELA H RAMSEY  
05/20/2011

**Patwardhan, Swati**

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**From:** Patwardhan, Swati  
**Sent:** Wednesday, May 11, 2011 5:20 PM  
**To:** 'Joy Vanderwal'  
**Cc:** Ramsey, Angela; Ronald Gunn  
**Subject:** RE: Intelliject: NDA 201,739

Dear Ms. Vanderal,

We request additional information as follows:

(1) Validation protocol 7.5.1.17 (submitted in the 29-APR-2011 Amendment) states that the endotoxin level for [REDACTED] (b) (4)

(2) Please provide representative [REDACTED] (b) (4)

(3) Please clarify whether validation is conducted on each and every batch of [REDACTED] (b) (4) to verify that the endotoxin acceptance criterion has been achieved.

(4) Protocol 7.5.1.17 includes a [REDACTED] (b) (4)

We propose to discuss these questions in the teleconference tomorrow afternoon at 3:00 pm (EST). Please confirm, if it is convenient at your end.

Do not hesitate to call me for any further questions.

Swati Patwardhan  
Regulatory Health Project Manager for Quality  
Office of New Drug Quality Assessment (ONDQA)  
Center of New Drug Evaluation and Research  
Phone: 301-796-4085  
Fax: 301-796-9748

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/s/  
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SWATI A PATWARDHAN  
05/12/2011

**Patwardhan, Swati**

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**From:** Patwardhan, Swati  
**Sent:** Monday, May 09, 2011 12:04 PM  
**To:** Joy Vander Wal  
**Subject:** RE: NDA 201739 - Intelliject IR

Dear Ms. Vander Wal,

Regarding media fill simulations conducted in support of the subject NDA we request the following:

1. Please provide a justification for why media fill simulations are conducted in Room (b) (4) rather than the room proposed for product fill: Room (b) (4). Are the fill processes and fill machinery in each room identical?
2. Please identify the container closure system used for media fill. Is it identical to the (b) (4) proposed for Epinephrine Injection USP 1:1000? If not please provide a justification.
3. The text on page 24 of Section 3.2.P.3.5.4 states that (b) (4) was utilized please provide confirmation that this medium met growth promotion acceptance criteria.
4. The acceptance criteria for fill simulation includes a requirement that a minimum of (b) (4) containers be filled per trial (Section 3.2.P.3.5.4, Page 24). Table 3.2.P.3.5-5 presents results for simulations conducted with (b) (4) cartridges. Please clarify why the number of cartridges filled in these trials is less than what is stipulated by the acceptance criteria.

Pleas provide your response by COB May 10, 2011.

Thank you

Swati Patwardhan  
Regulatory Health Project Manager for Quality  
Office of New Drug Quality Assessment (ONDQA)  
Center of New Drug Evaluation and Research  
Phone: 301-796-4085  
Fax: 301-796-9748

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/s/  
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SWATI A PATWARDHAN  
05/09/2011

# MEMORANDUM OF TELECON

DATE: April 15, 2011

APPLICATION NUMBER: NDA 201739

BETWEEN:

Name:

**Intelliject:**

Ronald D. Gunn, Vice President Drug Development and Regulatory Affairs  
Mark Licata, Vice President Industrialization & Quality  
Evan Edwards, Vice President Product Development

**Pharmatech Associates, Inc.:**

Gregg Ekberg, Chief Operating Officer  
William DeVincenzi, Director of Quality Assurance

**RRD International, LLC:**

Margaret Kautz, Senior Regulatory Affairs Specialist

AND

Name:

**FDA**

Isabel Tejero, Compliance Reviewer, CDRH  
Ying Wang, Quality Reviewer  
Prasad Peri, Quality Assessment Lead  
Milva Melendez, Device Manufacturing Product Quality  
Brian Porter, Medical Reviewer  
Susan Limb, Medical Team Leader  
Angela Ramsey, Regulatory Project Manager  
Vertleen Covington, Office of Compliance

SUBJECT: Comparability Protocol for NDA 201739

This is a memo to file regarding telephone conversation on April 15, 2011, with Intelliject to discuss comparability protocol submitted with NDA 201739. CDRH informed Intelliject that there were two issues with the comparability protocol:

1. The current site manufacturing site has not been inspected and CDRH has not seen data to validate the manufacturing process.
2. CDRH has concerns with physical movement of assembly-line from one site to another without process validation data. CDRH requires additional information such as the installation of the machinery, the assembly process, and

process validation to compare with the current manufacturing process.

CDRH stated that this data is needed for review before the CDRH can provide an opinion about the manufacturing process and make recommendations on the comparability protocol.

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Angela Ramsey RN, MSN  
Senior Regulatory Project Manager

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/s/  
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ANGELA H RAMSEY  
04/29/2011



NDA 201-739

**INFORMATION REQUEST**

Intelliject Inc.  
Attention: Joy Vanderwal  
111 Virginia Street, Suite 405  
Richmond, VA 23219

Dear Ms. Vanderwal:

Please refer to your New Drug Application (NDA) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Epinephrine Auto-Injector.

We also refer to you're the original submission, containing comparability protocol for device manufacturing change and have the following comments and information requests for the (b) (4), responsible for automation of the EAI final assembly line, packaging and inspection. We request a prompt written response in order to continue our evaluation of your NDA.

1. Does (b) (4) have other processes at the same facility comparable to the new automated assembly the firm is proposing to set up?
2. What manufacturing changes will be conducted to put the new data matrix in the device housing?
3. Does the addition of the data matrix have any impact on the final product safety and effectiveness?

To properly evaluate the manufacturing process of the new assembly lines, CDRH would like to have access to the following information at the time of the review:

4. A diagram of the proposed new manufacturing site.
5. A description of the proposed process flow.
6. A description of the equipment and processes that are the subject of the site change.
7. A list of the processes that will be fully verified, where appropriate, and the verification methods to be used.

8. The process validation or revalidation master plan (including software validation where applicable)
9. The process validation or revalidation information for all processes that were validated. It is recommended that you provide the process validation or revalidation protocols, and completed reports for all the processes that required validation. Also, provide all their completed validation activities prior to submitting the comparability study results.
10. The procedures for environmental and contamination controls, if such conditions could adversely affect the device.
11. Procedures that explain how inspection, measuring, and test equipment are routinely calibrated, inspected, checked, and maintained. The submission of the complete list of the procedure titles and a sample of the most relevant procedures may be enough for the evaluation. If granted, a statement indicating that procedures are the same as previously submitted should be provided.

If you have any questions, call Swati Patwardhan, Regulatory Project Manager, at 301-796-4085.

Sincerely,

*{See appended electronic signature page}*

Prasad Peri, Ph.D.  
Branch Chief, Branch VIII  
Division of New Drug Quality Assessment III  
Office of New Drug Quality Assessment  
Center for Drug Evaluation and Research

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/s/  
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PRASAD PERI  
04/15/2011

**MEMORANDUM**

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

**DATE:** March 30, 2011

**TO:** Joy Vanderwal RRD International  
C/o Intelliject

**FROM:** Angela Ramsey

**SUBJECT:** PDUFA goal date for Labeling Discussions

**APPLICATION/DRUG:** NDA 201739/Epinephrine Auto-Injector

Angela Ramsey contacted Joy Vanderwal on behalf of Intelliject via telephone March 30, 2011, to inform Intelliject that the corrected goal date for labeling discussion for Epinephrine Auto-Injector is July 8, 2011.

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/s/  
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ANGELA H RAMSEY  
03/30/2011

## MEMORANDUM OF TELECON

DATE: March 15, 2011

APPLICATION NUMBER: NDA 201739

BETWEEN:

Name: Joy Vanderwal RRD International  
Ronald Gunn  
Phone: 301-762-6100 x119  
Representing: Intelliject

AND

Name: Brian Porter, Medical Reviewer  
Susan Limb, Medical Team Leader  
Angela Ramsey, Regulatory Project Manager  
Division of Pulmonary, Allergy, and Rheumatology Products

SUBJECT: Update on review of NDA 201739

This is a memo to file regarding telephone conversation on March 15, 2011, with Intelliject representatives to provide a status update of the review. The Division informed Intelliject that the NDA is still under review. The team has reviewed the audio script and recommended minor language edits. The team will send comments this week. The Division inquired on Intelliject's plans to submit proposed proprietary name. Intelliject stated that they plan to submit proposed proprietary names by mid-April. The Division also requested additional 1-2 samples of the device.

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Angela Ramsey RN, MSN  
Senior Regulatory Project Manager

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ANGELA H RAMSEY  
03/23/2011



Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation II

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**FACSIMILE TRANSMITTAL SHEET**

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Date: March 15, 2011

To: Joy Vanderwal	From: Angela Ramsey Regulatory Project Manager
Company: Intelliject Inc.	Division of Pulmonary, Allergy, and Rheumatology Drug Products
Fax number: 804-545-6219	Fax number: 301-796-9728
Phone number: 804-545-6376	Phone number: 301-796-2284

Subject: NDA 201739 Proposed EAI device script

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Total no. of pages including cover:

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Comments:

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NDA 201739

We are reviewing your submissions dated, November 30, 2010, and March 8, 2011, and we have the following comments regarding your device script :

We propose changes to the EAI device script to improve patient comprehension and reduce potential administration errors (see attached). We request that you provide an assessment of use-related risks to determine whether additional human factor testing will be required to revalidate the proposed script changes. We request a response by April 15, 2011

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

If you have any additional questions regarding the NDA application, you may contact Mrs. Angela Ramsey, Senior Regulatory Management Officer, at 301-796-2284.

Drafted by: CB/March 11, 2011; SL//March 11, 2011; QN/March 14, 2011  
Initialed by: SB/March 15, 2011;  
Finalized: AR/March 15, 2011

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SADAF NABAVIAN

03/15/2011

SN for AR



NDA 201739

**PROPRIETARY NAME REQUEST  
WITHDRAWN**

Intelliject, Inc.  
c/o RRD International, LLC.  
7361 Calhoun Place  
Suite 510  
Rockville, MD 20855

ATTENTION: Joy Vander Wal, RN, BSN  
Senior Director, Regulatory Affairs

Dear Ms. Vander Wal:

Please refer to your New Drug Application (NDA) dated September 29, 2010, received September 29, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epinephrine Injection, 0.15 mg and 0.3 mg.

We acknowledge receipt of your February 8, 2011 correspondence, on February 8, 2011, notifying us that you are withdrawing your request for review of the proposed proprietary names, (b) (4) and (b) (4). This proposed proprietary name request is considered withdrawn as of February 8, 2011.

We note that you have not proposed an alternate proprietary name for review. If you intend to have a proprietary name for this product, a new request for a proposed proprietary name review should be submitted. (See the Guidance for Industry, *Contents of a Complete Submission for the Evaluation of Proprietary Names*, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, call Nichelle Rashid, Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-3904. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Angela Ramsey at (301) 796-2284.

Sincerely,

*{See appended electronic signature page}*

Carol Holquist, RPh  
Director  
Division of Medication Error Prevention and Analysis  
Office of Surveillance and Epidemiology  
Center for Drug Evaluation and Research

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CAROL A HOLQUIST  
03/09/2011

**Patwardhan, Swati**

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**From:** Patwardhan, Swati  
**Sent:** Tuesday, March 08, 2011 2:23 PM  
**To:** 'Joy Vanderwal'  
**Cc:** Ronald Gunn; Margaret Kautz; Frank Hurley  
**Subject:** RE: Intelliject: NDA 201-739

Hello Ms. Vander Wal,

We are reviewing the CMC aspect of the NDA application 201,739 and need additional information to continue the review of the application as provided below:

1.  (b) (4)

2.  (b) (4)

Please acknowledge the receipt. and provide a tentative time line for the amendment response.

Thank you

Reference ID: 2915277

3/8/2011

Swati Patwardhan  
Regulatory Health Project Manager for Quality  
Office of New Drug Quality Assessment (ONDQA)  
Center of New Drug Evaluation and Research  
Phone: 301-796-4085  
Fax: 301-796-9748

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SWATI A PATWARDHAN  
03/08/2011



FACSIMILE TRANSMITTAL SHEET	
<b>DATE:</b> February 28, 2011	
<b>To:</b> Joy Vander Wal	<b>From:</b> Swati Patwardhan Regulatory Health Project Manager Office of Pharmaceutical Science Office of New Drug Quality Assessment
<b>Company:</b> Intelliject Inc.	
<b>Fax number:</b> 804-545-6219	<b>Fax number:</b> 301-796-9748
<b>Phone number:</b> 804-545-6376	<b>Phone number:</b> 301-796-4085
<b>Subject:</b> NDA 201-739	
<b>Total # of pages including cover:</b> 3	
<b>Comments:</b>  <b>Information Request Letter</b>	
<b>Original document to be mailed:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

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NDA 201-739

Your submission dated September 29, 2010, to NDA 201-739 is currently under review. We have the following request for information:

**Provide updated information on identification and characterization for the specified unidentified (b) (4) in the drug product, and provide a safety assessment.**

We request a response by March 18, 2011. If you have any additional questions regarding the NDA application, you may contact Swati Patwardhan, Regulatory Project Manager, at 301-796-4085.

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/s/  
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SWATI A PATWARDHAN  
02/28/2011



Food and Drug Administration  
 Center for Drug Evaluation and Research  
 Office of Drug Evaluation II

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**FACSIMILE TRANSMITTAL SHEET**

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**DATE: February 28, 2011**

<b>To: Joy Vanderwal</b>	<b>Angela Ramsey</b>
<b>Company: Intelliject Inc.</b>	<b>From: Senior Regulatory Project Manager</b>
<b>Fax number: 804-545-6219</b>	<b>Division of Pulmonary, Allergy, and Rheumatology Products</b>
<b>Phone number: 804-545-6376</b>	<b>Fax number: 301-796-9728</b>
	<b>Phone number: 301-796-2284</b>
<b>Subject: NDA 201-739</b>	

**Total no. of pages including cover: 2**

**Comments:**

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Your submission dated September 29, 2010, to NDA 201-739 is currently under review. We have the following request for information:

*We note a discrepancy in the rate of tachycardia reported in the Clinical Study Report for INT0802. Table 14.3.1.5 indicates increased heart rate occurred after 24 RLD injections or 17.8% of 135 RLD doses, while the summary text in Section 12.5.1 indicates tachycardia occurred after 25 RLD injections or 18.5% of all RLD injections. Clarify this discrepancy.*

We request a response by March 14, 2011. If you have any additional questions regarding the NDA application, you may contact CDR Angela Ramsey, Senior Regulatory Management Officer, at 301-796-2284.

NDA 201-739

Drafted by: PB/February 25, 2011

Initialed by: SL/February 25, 2011; SB/February 28, 2011

Finalized by: AR/February 28, 2011

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/s/  
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ANGELA H RAMSEY  
02/28/2011



Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation II

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**FACSIMILE TRANSMITTAL SHEET**

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**Date:** February 24, 2011

<b>To:</b> Joy Vanderwal	<b>From:</b> Angela Ramsey Regulatory Project Manager
<b>Company:</b> Intelliject Inc.	Division of Pulmonary, Allergy, and Rheumatology Drug Products
<b>Fax number:</b> 804-545-6219	<b>Fax number:</b> 301-796-9728
<b>Phone number:</b> 804-545-6376	<b>Phone number:</b> 301-796-2284

**Subject:** NDA 201739 Clin Pharm IR fax

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**Total no. of pages including cover:**

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**Comments:**

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NDA 201739

We are reviewing your submission dated, September 29, 2010, and have the following requests for information:

1. The dataset PKPARMCH (found in 5.3.1.2.25.3.1.Analysis Dataset, under the title "Study INT0802 - Analysis - PKPARMCH - PK Parameters-Chng Bsl") and the dataset PKPARMOB (found in 5.3.1.2.25.3.1.Analysis Dataset, under the title "Study INT0802 - Analysis - PKPARMOB - PK Parameters-Observed") appear to be identical. It appears that the dataset PKPARMOB was repeated in the submission under the title PKPARMCH. Submit the proper datasets PKPARMCH and PKPARMOB.
2. There are several SAS PROC MIXED outputs in the submission. One example is titled "Bioequivalence for AUC\_inf, Raw Observations", found on pages 250-253 of 16.1.9 "Documentation of Statistical Methods".
  - a. Describe how the variables mu\_T, mu\_R, gamma1, gamma2, gamma3, gamma4, gamma5, gamma6, and gamma7 were defined and constructed.
  - b. Submit the SAS PROC MIXED program statements that were used to produce these outputs.
3. There are two reference treatments. However, it is not clear what treatment, AUC0-Rtmax (shown in Tables 10 & 11) corresponds to. Explain, how it was calculated. Specify the location of the data source, programming code, and algorithm used for AUC0-Rtmax calculation if already submitted. If not, submit these items.

Submit your response to me via telephone facsimile to 301-796-9728 or email at [Angela.Ramsey@fda.hhs.gov](mailto:Angela.Ramsey@fda.hhs.gov) by COB on February 28, 2011. Your response will subsequently need to be submitted officially to the NDA.

If you have any additional questions regarding the NDA application, you may contact Mrs. Angela Ramsey, Senior Regulatory Management Officer, at 301-796-2284.

Drafted by: Ramsey/February 24, 2011

Initialed by: Barnes/February 24, 2011; LZ/February 24, 2011

Finalized: Ramsey/February 24, 2011

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/s/  
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ANGELA H ROBINSON  
02/24/2011

## MEMORANDUM

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

**MEETING DATE:** February 2, 2010  
**TIME:** 12:30 PM  
**LOCATION:** WO 22, Room 4266  
**APPLICATION:** NDA 201739  
**DRUG NAME:** Epinephrine Auto-Injector 0.15 mg and 0.3 mg (epinephrine injection USP 1:1000)  
**TYPE OF MEETING:** Proposed Primary Proprietary Name  
**MEETING CHAIR:** Carol Holquist, R.Ph.  
**MEETING RECORDER:** Nichelle Rashid

### FDA ATTENDEES:

Carol Holquist, R.Ph., Director, DMEPA  
Todd Bridges, R.Ph., Team Leader, DMEPA  
Colleen Brennan, R.Ph., Safety Evaluator, DMEPA  
Kellie Taylor, PharmD, MPH, Associate Director, DMEPA  
Samantha Cotter, PharmD, BCPS, FDA/ISMP Safe Medication Management Fellow, DMEPA  
Sean Bradley, R.Ph., OSE RPM Team Leader  
Nichelle Rashid, OSE RPM

### EXTERNAL CONSTITUENT ATTENDEES:

Ronald D. Gunn, VP Drug Development and Regulatory Affairs, Intelliject, Inc.  
Eric Edwards, Chief Science Officer, Intelliject, Inc.  
Jerry Phillips, President and CEO, Drug Safety Institute  
Bryan Downing, VP, Sanofi-Aventis  
Joy K. Vander Wal, Sr. Director, Regulatory Affairs, RRD International, LLC

### BACKGROUND:

Intelliject, Inc. submitted the proposed primary proprietary name, (b) (4) and the alternate proposed proprietary name, (b) (4) for NDA 201739, Epinephrine Auto-Injector 0.15 mg and 0.3 mg (epinephrine injection USP 1:1000) on September 29, 2010. On December 28, 2010, an unacceptable letter for the proposed proprietary name, (b) (4) was sent to the sponsor. The letter stated that (b) (4) is misleading because it may be confused with the currently

marketed proprietary name (b) (4) due to its similarity in spelling. On January 20, 2011, Intelliject, Inc. submitted a reconsideration of the proprietary name, (b) (4).

### **MEETING OBJECTIVES:**

DMEPA requested this teleconference to inform the sponsor of their concerns with the reconsideration of the proposed primary proprietary name, (b) (4) and the alternate proposed proprietary name, (b) (4).

### **DISCUSSION POINTS:**

DMEPA conveyed the following to the sponsor:

We find the primary proposed proprietary name, (b) (4) unacceptable based on 21 CFR 201.10(c)(5), which states “The labeling of a drug may be misleading by reason of designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.” It was stated that the spelling and pronunciation are considered prior to the product characteristics. Based on the spelling of (b) (4), the proposed proprietary name was denied. The decision remained the same based on the spelling of the name.

We also conducted a preliminary assessment of your alternate proposed proprietary name, (b) (4) and determined that it is also unacceptable. (b) (4) has orthographic similarity with the currently marketed product, (b) (4).

The sponsor agreed to the withdrawal the proprietary name submission for (b) (4) and plan to submit another name. The sponsor is not planning on submitting the proposed proprietary name, (b) (4).

DMEPA also commented on the proposed package labeling which included a sound-wave symbol in the trade name logo. They informed the sponsor that this type of material is classified as intervening matter and in most cases found not acceptable. DMEPA advised the sponsor that package labeling and audio-script reviews and comments will done at a later time in coordination with other FDA review offices, namely OND and CDRH.

Addendum:

On February 8, 2011, the sponsor submitted a withdrawal for the proposed proprietary names, (b) (4) and (b) (4).

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/s/  
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NICHELLE E RASHID  
02/11/2011

TODD D BRIDGES  
02/11/2011



Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation II

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**FACSIMILE TRANSMITTAL SHEET**

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**Date:** January 25, 2011

<b>To:</b> Joy Vanderwal	<b>From:</b> Angela Ramsey Regulatory Project Manager
<b>Company:</b> Intelliject Inc.	Division of Pulmonary, Allergy, and Rheumatology Drug Products
<b>Fax number:</b> 804-545-6219	<b>Fax number:</b> 301-796-9728
<b>Phone number:</b> 804-545-6376	<b>Phone number:</b> 301-796-2284

**Subject:** NDA 201739 Labeling Rebuttal package

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**Total no. of pages including cover:**

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**Comments:**

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**Document to be mailed:** YES XNO

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NDA 201739

We are reviewing your submissions dated, September 29, 2010, and January 20, 2011, and we have the following comments regarding proprietary name review:

1. In the rebuttal package dated January 20, 2011, the labels are different than those submitted to the application on September 29, 2010. Confirm that the labels and labeling submitted on September 29, 2010, are the labels intended for marketing. If the proposed labeling is different than what was submitted on September 29, 2010, submit revised labels and labeling to the NDA as soon as possible.
2. In the submission dated September 29, 2010 two labeling color schemes were submitted for the Trainer Device (grey/black/white), and the Trainer Device Carton labeling (blue/green/white). Please confirm the following:
  - A. The color scheme for the Trainer Device and Labeling
  - B. That you will be dispensing the Trainer Device separately from the active devices in its own carton

If you have any questions regarding the proprietary name review, please contact Nichelle Rashid at 301-796-3904.

If you have any additional questions regarding the NDA application, you may contact Mrs. Angela Ramsey, Senior Regulatory Management Officer, at 301-796-2284.

Drafted by: Ramsey/January 25, 2011  
Initialed by: Barnes/January 25, 2011; CB/January 27, 2011  
Finalized: Ramsey/January 27, 2011

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/s/  
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ANGELA H ROBINSON  
01/27/2011



NDA 201739

**INFORMATION REQUEST**

Intelliject Inc.  
111 Virginia Street, Suite 405  
Richmond, VA 23219

Attention: Ronald Gunn, MS, MBA  
Vice President

Dear Mr Dunn:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epinephrine Auto-Injector, 0.15 and 0.3mg.

We also refer to your submission dated, September 29, 2010, and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

Clinical

1. We note that the proposed indication for EAI differs from the approved indication for the reference listed drug. Provide data to support the specific additional claims, or amend the proposed label to remove any unsupported claims.

Clinical Pharmacology

2. As stated in the pre-NDA meeting comments, we recognize that you have adopted the novel reference replicated-treatment study design and the statistical data analysis using reference-scaling average BE approach that has been proposed in recent literature by the Agency. Based on the fact that this new method has not yet been part of any published FDA Guidance for Industry, the PK analysis results based on this method will be a review issue.

If you have any questions, call Angela Ramsey, Senior Regulatory Project Manager, at (301) 796-2284.

Sincerely,

Badrul A. Chowdhury, M.D., Ph.D.  
Director  
Division of Pulmonary, Allergy, and Rheumatology  
Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/  
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LYDIA I GILBERT MCCLAIN  
01/13/2011  
Acting Division Director



NDA 201739

**PROPRIETARY NAME REQUEST  
UNACCEPTABLE**

Intelliject, Inc.  
111 Virginia Street  
Suite 405  
Richmond, VA 23219

ATTENTION: Ronald D. Gunn, MS, MBA  
Vice President, Drug Development & Regulatory Affairs

Dear Mr. Gunn:

Please refer to your New Drug Application (NDA) dated September 29, 2010, received September 29, 2010, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Epinephrine Injection, 0.3 mg/0.3 mL and 0.15 mg/0.15 mL.

We also refer to your September 29, 2010, correspondence, received September 29, 2010, requesting review of your proposed proprietary name, (b) (4). We have completed our review of this proposed proprietary name and have concluded that this name is unacceptable for the following reasons.

The proposed name, (b) (4) is misleading because it may be confused with the currently marketed proprietary name (b) (4) due to its similarity in spelling. Not only are these products similar in spelling but also appear similar when scripted because the names share three letters and these letters appear in the same position of each name (see below).

(b) (4)

Despite the differing product characteristics among these products, the similarity in spelling and appearance of the name when scripted increases the risk of confusion between this name pair. Post-marketing errors with other similarly spelled name pairs has demonstrated that differing product characteristics have been insufficient to minimize confusion between proprietary names that are spelled too similar or appear too similar when scripted. Thus, we object to the proposed name based on 21 CFR 201.10 (c)(5), which states “The labeling of a drug may be misleading by reason of designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.”

We note that you have proposed an alternate proprietary name in your submission dated September 29, 2010. In order to initiate the review of the alternate proprietary name, (b) (4), you must submit a new complete request for proprietary name review. The review of this alternate name will not be initiated until the new submission is received.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Nichelle Rashid, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-3904. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Angela Ramsey at (301) 796-2284.

Sincerely,

*{See appended electronic signature page}*

Carol Holquist, RPh  
Director  
Division of Medication Error Prevention and Analysis  
Office of Surveillance and Epidemiology  
Center for Drug Evaluation and Research

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/s/  
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DENISE P TOYER on behalf of CAROL A HOLQUIST  
12/28/2010

## MEMORANDUM

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

**MEETING DATE:** December 14, 2010  
**TIME:** 11:30 AM  
**LOCATION:** WO 22 Room 4396  
**APPLICATION:** NDA 201739  
**DRUG NAME:** Epinephrine Auto-Injector 0.15 mg and 0.3 mg (epinephrine injection USP 1:1000)  
**TYPE OF MEETING:** Proposed Primary Proprietary Name  
**MEETING CHAIR:** Colleen Brennan, R.Ph.  
**MEETING RECORDER:** Nichelle Rashid

### FDA ATTENDEES:

Todd Bridges, R.Ph., Team Leader, DMEPA  
Colleen Brennan, R.Ph., Safety Evaluator, DMEPA  
Sean Bradley, R.Ph., SRPM Team Leader  
Nichelle Rashid, SRPM

### EXTERNAL CONSTITUENT ATTENDEES:

Ronald D. Gunn, VP Drug Development and Regulatory Affairs, Intelliject, Inc.  
Neil Hughs, VP Marketing, Intelliject, Inc.  
Eric Edwards, Chief Science Officer, Intelliject, Inc.  
Jerry Phillips, President and CEO, Drug Safety Institute  
Bryan Downing, VP, Sanofi-Aventis

### BACKGROUND:

Intelliject, Inc. submitted the proposed primary proprietary name, (b) (4) and the alternate proposed proprietary name, (b) (4) for NDA 201739, Epinephrine Auto-Injector 0.15 mg and 0.3 mg (epinephrine injection USP 1:1000) on September 29, 2010.

### MEETING OBJECTIVES:

DMEPA requested this teleconference to inform the sponsor of their concerns with the proposed primary proprietary name, (b) (4) and the alternate proposed proprietary name, (b) (4) and to provide the sponsor with options regarding a proprietary name for their proposed product.

## **DISCUSSION POINTS:**

DMEPA conveyed the following to the sponsor:

In our assessment of the primary proposed proprietary name, (b) (4), we identified that it is vulnerable to name confusion with the currently marketed product (b) (4) due to orthographic similarities. The names are of similar length and are nearly identical in spelling.

Despite the product characteristic differences, our post-marketing experience with other similarly spelled name pairs has shown that differing product characteristics have been insufficient in differentiating two products when the proprietary names are nearly identical in spelling, such as the case with (b) (4) and (b) (4).

Thus, we find the primary proposed proprietary name, (b) (4) unacceptable based on 21 CFR 201.10(c)(5), which states “The labeling of a drug may be misleading by reason of designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.”

We also conducted a preliminary assessment of your alternate proposed proprietary name, (b) (4) and determined that it is also unacceptable. (b) (4) has orthographic similarity with the currently marketed product, (b) (4). These names share three letters (b) (4) in similar positions and the remaining letters may look similar when scripted. Additionally, both of these products can be ordered with a sig of “use as directed” and a quantity of #1, which increases the potential for confusion. We believe that these orthographic similarities and overlapping product characteristics may lead to confusion that may contribute to medication errors.

DMEPA gave the sponsor the option to withdraw the proprietary name request for (b) (4) and (b) (4) and submit an alternate name for review.

The sponsor agreed to evaluate the withdrawal option and to reply with an action plan by close of business, Thursday, December 16, 2010.

### **Addendum:**

The sponsor decided not to withdraw the proprietary name request for (b) (4) and (b) (4) via email on Thursday, December 16, 2010.

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/s/  
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NICHELLE E RASHID  
12/23/2010



NDA 201739

**FILING COMMUNICATION**

Intelliject Inc.  
111 Virginia Street, Suite 405  
Richmond, VA 23219

Attention: Ronald Gunn, MS, MBA  
Vice President

Dear Mr Dunn:

Please refer to your New Drug Application (NDA) dated and received September 29, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Epinephrine Auto-Injector, 0.15 and 0.3 mg.

We also refer to your submissions dated, November 4 and 11, 2010.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application is considered filed 60 days after the date we received your application. The review classification for this application is Standard. Therefore, the user fee goal date is July 29, 2011.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, midcycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by April 29, 2011.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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.

We acknowledge receipt of your request for a full deferral of pediatric studies for this application. Once we have reviewed your request, we will notify you if the full deferral request is denied.

If you have any questions, call Angela Ramsey, Senior Regulatory Project Manager, at (301) 796-2284.

Sincerely,

*{See appended electronic signature page}*

Badrul A. Chowdhury, M.D., Ph.D.  
Director  
Division of Pulmonary, Allergy, and Rheumatology  
Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/  
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ANGELA H ROBINSON  
11/19/2010

BADRUL A CHOWDHURY  
11/19/2010



NDA 201739

**NDA ACKNOWLEDGMENT**

Intelliject Inc.  
111 Virginia Street, Suite 405  
Richmond, VA 23219

Attention: Ronald Gunn  
Vice President

Dear Mr Dunn:

We have received your New Drug Application (NDA) submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: Epinephrine Auto-Injector

Date of Application: September 29, 2010

Date of Receipt: September 29, 2010

Our Reference Number: NDA 201739

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on November 28, 2010, in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

The NDA number provided above should be cited at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Pulmonary, Allergy, and Rheumatology Products  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm>

If you have any questions, call Angela Ramsey, Senior Regulatory Project Manager at (301) 796-2284.

Sincerely,

*{See appended electronic signature page}*

Sandy Barnes  
Chief, Project Management Staff  
Division of Pulmonary, Allergy, and Rheumatology  
Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/

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ANGELA H ROBINSON

10/21/2010

AR for SB