



NDA 201739

**TENTATIVE APPROVAL**

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

Attention: Ronald Gunn  
Vice President

Dear Mr Dunn:

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

We acknowledge receipt of your amendment(s) dated, November 4, 5, 12, and 30, and December 15 and 16, 2010, and January 20, 25, 27 and 31, February 1, 8, 10 and 11, March 2, 3, 9, 14, 17, 18, 21 and 24, April 1, 8, 19, 25, 26, 28 and 29, May 5, 10, 26, 27 and 31, June 1 and 7, and July 1 and 7, 2011.

This NDA provides for the use of e-cue (epinephrine) 0.3 mg (0.3 mg/0.3ml) and 0.15 mg (0.15 mg/0.15ml) for emergency treatment of allergic reactions including anaphylaxis.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the package insert, text for the patient information leaflet and trainer information leaflet, carton and immediate container labels. This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product] This determination is subject to change on the basis of any new information that may come to our attention.

Your application contains certifications to each of the patents under section 505(b)(2)(A)(iv) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications").

Section 505(c)(3)(C) of the Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of forty-five days from the date

the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the Act.

In addition, you have notified the Agency that the patent owner and/or approved application holder has initiated a patent infringement suit against you with respect to patent 7,794,432 B2 in the United States District Court, District of Delaware. Therefore, final approval cannot be granted until:

1. a. expiration of the 30-month period provided for in Section 505(c)(3)(C) beginning on the date of receipt of the 45-day notice required under Section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or
- b. the date the court decides that the patent is invalid or not infringed as described in section 505(c)(3)(C)(i), (ii), (iii,) or (iv) of the Act, or,
- c. the listed patent has expired, and
2. we are assured there is no new information that would affect whether final approval should be granted.

Two or six months prior to the expiration of the patent, as appropriate, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. Any changes to in the conditions outlined in this NDA require our review before final approval and the goal date for our review will be set accordingly. Your amendment should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letter before the expiration of the patent, you should amend your application accordingly.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

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

ENCLOSURE(S):

Patient Insert  
Patient Instructions for Use  
Trainer Instructions for Use  
Content of Labeling  
Carton and Container Labeling

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**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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BADRUL A CHOWDHURY  
07/29/2011