

1282-7-55-6 10:11

February 1, 2007

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Cardiovascular and Renal Products  
5901-B Amundale Road  
Beltsville, MD 20705-1266

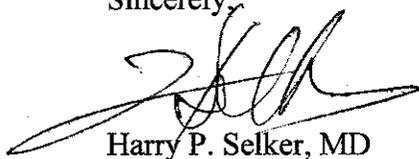
RE: IND 70,376, IMMEDIATE Trial,  
Massachusetts region pre-enrollment public disclosure materials

Dear Dr. Stockbridge:

The documents contained in this submission are copies of the information that was used for the IMMEDIATE Trial pre-enrollment public disclosure (per 21CFR 50.24(a)(7)(ii)) in the Massachusetts region. The public disclosure took place in Brockton, Massachusetts and in the communities served by Emerson Hospital Emergency Medical Services.

Please do not hesitate to contact us with any questions.

Sincerely,



Harry P. Selker, MD  
Study Chair/Principal Investigator

19955-0158

RPT 21

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 PUBLIC HEALTH SERVICE  
 FOOD AND DRUG ADMINISTRATION  
**INVESTIGATIONAL NEW DRUG APPLICATION (IND)**  
 (TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

Form Approved: OMB No. 0910-0014.  
 Expiration Date: January 31, 2006  
 See OMB Statement on Reverse.

NOTE: No drug may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40).

1. NAME OF SPONSOR Harry P. Selker, MD, MSPH	2. DATE OF SUBMISSION 02/01/2007
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3. ADDRESS (Number, Street, City, State and Zip Code) Institute for Clinical Research and Policy Studies, Tufts-New England Medical Center 750 Washington St., #63 Boston, MA 02111	4. TELEPHONE NUMBER (Include Area Code) 617-636-8787
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5. NAME(S) OF DRUG (Include all available names: Trade, Generic, Chemical, Code) Glucose-insulin-Potassium solution	6. IND NUMBER (If previously assigned) 70376
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7. INDICATION(S) (Covered by this submission)  
Acute Coronary Syndromes

8. PHASE(S) OF CLINICAL INVESTIGATION TO BE CONDUCTED:  
 PHASE 1  PHASE 2  PHASE 3  OTHER \_\_\_\_\_  
 (Specify)

9. LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), DRUG MASTER FILES (21 CFR Part 314.420), AND PRODUCT LICENSE APPLICATIONS (21 CFR Part 601) REFERRED TO IN THIS APPLICATION.

10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted.

SERIAL NUMBER  
0007

11. THIS SUBMISSION CONTAINS THE FOLLOWING: (Check all that apply)

<input type="checkbox"/> INITIAL INVESTIGATIONAL NEW DRUG APPLICATION (IND)	<input type="checkbox"/> RESPONSE TO CLINICAL HOLD
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PROTOCOL AMENDMENT(S): <input type="checkbox"/> NEW PROTOCOL <input type="checkbox"/> CHANGE IN PROTOCOL <input type="checkbox"/> NEW INVESTIGATOR	INFORMATION AMENDMENT(S): <input type="checkbox"/> CHEMISTRY/MICROBIOLOGY <input type="checkbox"/> PHARMACOLOGY/TOXICOLOGY <input type="checkbox"/> CLINICAL	IND SAFETY REPORT(S): <input type="checkbox"/> INITIAL WRITTEN REPORT <input type="checkbox"/> FOLLOW-UP TO A WRITTEN REPORT <input type="checkbox"/> ANNUAL REPORT <input type="checkbox"/> GENERAL CORRESPONDENCE <input checked="" type="checkbox"/> OTHER <u>Public Disclosure Materials</u> (Specify)
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RESPONSE TO FDA REQUEST FOR INFORMATION  
 REQUEST FOR REINSTATEMENT OF IND THAT IS WITHDRAWN, INACTIVATED, TERMINATED OR DISCONTINUED

**CHECK ONLY IF APPLICABLE**

JUSTIFICATION STATEMENT MUST BE SUBMITTED WITH APPLICATION FOR ANY CHECKED BELOW. REFER TO THE CITED CFR SECTION FOR FURTHER INFORMATION.

TREATMENT IND 21 CFR 312.35(b)  TREATMENT PROTOCOL 21 CFR 312.35(a)  CHARGE REQUEST/NOTIFICATION 21 CFR 312.7(d)

**FOR FDA USE ONLY**

CDR/DBIND/DGD RECEIPT STAMP	DDR RECEIPT STAMP	DIVISION ASSIGNMENT:
		IND NUMBER ASSIGNED:

12.

**CONTENTS OF APPLICATION**This application contains the following items: *(Check all that apply)*

1. Form FDA 1571 [21 CFR 312.23(a)(1)]
2. Table of Contents [21 CFR 312.23(a)(2)]
3. Introductory statement [21 CFR 312.23(a)(3)]
4. General Investigational plan [21 CFR 312.23(a)(3)]
5. Investigator's brochure [21 CFR 312.23(a)(5)]
6. Protocol(s) [21 CFR 312.23(a)(6)]
- a. Study protocol(s) [21 CFR 312.23(a)(6)]
- b. Investigator data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572
- c. Facilities data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572
- d. Institutional Review Board data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572
7. Chemistry, manufacturing, and control data [21 CFR 312.23(a)(7)]
- Environmental assessment or claim for exclusion [21 CFR 312.23(a)(7)(iv)(e)]
8. Pharmacology and toxicology data [21 CFR 312.23(a)(8)]
9. Previous human experience [21 CFR 312.23(a)(9)]
10. Additional information [21 CFR 312.23(a)(10)]

13. IS ANY PART OF THE CLINICAL STUDY TO BE CONDUCTED BY A CONTRACT RESEARCH ORGANIZATION?  YES  NO
- IF YES, WILL ANY SPONSOR OBLIGATIONS BE TRANSFERRED TO THE CONTRACT RESEARCH ORGANIZATION?  YES  NO
- IF YES, ATTACH A STATEMENT CONTAINING THE NAME AND ADDRESS OF THE CONTRACT RESEARCH ORGANIZATION, IDENTIFICATION OF THE CLINICAL STUDY, AND A LISTING OF THE OBLIGATIONS TRANSFERRED.

14. NAME AND TITLE OF THE PERSON RESPONSIBLE FOR MONITORING THE CONDUCT AND PROGRESS OF THE CLINICAL INVESTIGATIONS

Joni Beshansky, RN, MPH- Co-Principal Investigator, Project Director

15. NAME(S) AND TITLE(S) OF THE PERSON(S) RESPONSIBLE FOR REVIEW AND EVALUATION OF INFORMATION RELEVANT TO THE SAFETY OF THE DRUG

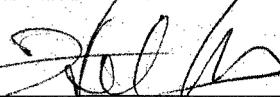
Donald E. Cutlip, MD

I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set fourth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

16. NAME OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE

Harry P. Selker, MD, MSPH

17. SIGNATURE OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE



18. ADDRESS (Number, Street, City, State and Zip Code)

Tufts-New England Medical Center  
750 Washington St., #63  
Boston, MA 02111

19. TELEPHONE NUMBER  
(Include Area Code)

617-636-8787

20. DATE

02/01/2007

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
CBER (HFM-99)  
1401 Rockville Pike  
Rockville, MD 20852-1448

Food and Drug Administration  
CDER (HFD-94)  
12229 Wilkins Avenue  
Rockville, MD 20852

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please **DO NOT RETURN** this application to this address

**IMMEDIATE Trial  
Pre-Enrollment Public Disclosure  
Massachusetts**

**Brockton**

The city of Brockton, Massachusetts has a diverse population of approximately 95,000 residents. The racial/ethnic breakdown of Brockton is approximately 62% white, 18% black or African American, 8% Hispanic or Latino, Asian 2%. The public disclosure plan was formulated to be inclusive of the diverse Brockton community.

Adults living in the community were the target audience. In order to reach a large number of people residing within the community multiple approaches were used and information was presented in English, Portuguese and Spanish, the predominant languages spoken by residents. Copies of the IMMEDIATE Trial pre-enrollment public disclosure information that was provided and or presented to the Brockton, Massachusetts community are included here.

**Emerson Hospital EMS**

Emerson Hospital Emergency Medical Services (EMS) provides 911 response 24 hours per day to 13 communities. The racial/ethnic breakdown of the communities served by Emerson Hospital EMS is predominantly white (91.1%). Copies of the IMMEDIATE Trial pre-enrollment public disclosure information that was provided to and or presented to the community residing in the Emerson Hospital EMS service are included. Adults living and working in the area were the target audience. Multiple media modes were used in order to reach a large number of people residing within the community.