VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code	Center No.	Patient No.	Date Completed
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FORM 01 - ENTRY CRITERIA & RANDOMIZATION

Personal Information

1. At the time the informed consent was signed, indicate the number of self-reported days of cocaine use in the past 30 days .....

2. Gender (1= Male 2 = Female) .....

3. Date of Birth ..... Mo Day Yr

Inclusion Criteria *(NS=Not Screened)*

4. Age is 18 or greater ..... 1 Yes 2 No 3 NS

5. DSM-IV diagnosis of cocaine dependence as determined by SCID ..... 1 Yes 2 No 3 NS

6. At least 3 positive urine BE specimens during the 14-day baseline period prior to randomization (6 total samples in 14 days; maximum 4 samples in 7 days) ..... 1 Yes 2 No 3 NS

7. Ability to understand and provide written informed consent ..... 1 Yes 2 No 3 NS

8. Use of an acceptable method of birth control (for males, mark "NS") ..... 1 Yes 2 No 3 NS

IF ANY OF Q. 4-8 IS ANSWERED "NO", PATIENT IS INELIGIBLE. PLEASE ENTER PATIENT SCREENING NUMBER ABOVE AND SIGN FORM.

Exclusion Criteria

9. Current dependence, defined by DSM-IV criteria, on any psychoactive substance other than cocaine, alcohol, nicotine, or marijuana. Physiological dependence on alcohol requiring medical detoxification. ..... 1 Yes 2 No 3 NS

10. Neurological or psychiatric disorders which require ongoing treatment or which would make medication compliance difficult; or subjects with current suicidal ideation ..... 1 Yes 2 No 3 NS

11. Serious medical illnesses including, but not limited to, uncontrolled hypertension, significant heart disease, angina, cardiovascular abnormality, hepatic or renal disorders, or any serious, potentially life-threatening or progressive medical illness other than addiction that may compromise patient safety or study conduct. ..... 1 Yes 2 No 3 NS

12. Mandated by the court to obtain treatment for cocaine dependence ..... 1 Yes 2 No 3 NS

13. Not seeking treatment for cocaine dependence ..... 1 Yes 2 No 3 NS

14. Anticipating elective surgery within 14 weeks of signing informed consent ..... 1 Yes 2 No 3 NS

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15. In the opinion of the investigator, subject is not expected to complete the protocol due to probable incarceration or relocation from the clinic area ..... 1 Yes 2 No 3 NS

16. AIDS ..... 1 Yes 2 No 3 NS

17. Active syphilis that has not been treated or refused treatment ..... 1 Yes 2 No 3 NS

18. History of neuroleptic malignant syndrome ..... 1 Yes 2 No 3 NS

19. Known or suspected hypersensitivity to selegiline, any monoamine oxidase inhibitor, or PEA ..... 1 Yes 2 No 3 NS

20. Known allergic or chronic dermatologic illness that might interfere with the STS absorption or which may be exacerbated by STS patch application ..... 1 Yes 2 No 3 NS

21. Hymenoptera allergy that requires carrying prophylactic epinephrine ..... 1 Yes 2 No 3 NS

22. Therapy with a medication that could interact adversely with selegiline, with the time of administration of study drug relative to other medications based on the longest time interval of a) five half lives of other medication or active metabolite(s), whichever is longer; b) two weeks, or c) interval recommended by other medication's product labeling (see Protocol, page 18, for medications that fall into this category) ..... 1 Yes 2 No 3 NS

23. Participated in any experimental study within 8 weeks, or have taken oral selegiline within 8 weeks of participation, or who have ever participated on a clinical trial utilizing the STS formulation ..... 1 Yes 2 No 3 NS

24. Pregnant or lactating female (the pregnancy test must be completed within 2 days of study drug administration) ..... 1 Yes 2 No 3 NS

25. In the opinion of the investigator, subject has clinically significant abnormal laboratory values ..... 1 Yes 2 No 3 NS

26. Electroconvulsive therapy within the past 90 days ..... 1 Yes 2 No 3 NS

27. Taken St. John's Wort, yohimbine, gingko biloba, or any other central nervous system active herbal preparations within 8 weeks of study entry ..... 1 Yes 2 No 3 NS

28. Therapy with any opiate substitutes (methadone, LAAM, buprenorphine) within 6 months of study entry ..... 1 Yes 2 No 3 NS

29. Diagnosis of adult asthma, including those with a history of acute asthma within the past 2 years, and those with current or recent (past 2 years) treatment with inhaled or oral beta-agonist or steroid therapy (due to potential serious adverse interactions with cocaine) ..... 1 Yes 2 No 3 NS

30. Actively using albuterol or other beta agonist medications, regardless of

formal diagnosis of asthma. (Inhalers are sometimes used by cocaine addicts to enhance cocaine delivery to the lungs.) ..... 1 Yes 2 No 3 NS

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31. Suspect for asthma but without formal diagnosis, 1) history of coughing and/or wheezing, 2) history of asthma and/or asthma treatment two or more years before, 3) history of other respiratory illness, e.g., complications of pulmonary disease (exclude if on beta agonists), 4) use of over-the-counter agonists or allergy medication for respiratory problems. A detailed history, physical exam, pulmonary consult, and pulmonary function tests should be performed prior to including or excluding from the study. Subjects with FEV_1<70 will be excluded. ..... 1 Yes 2 No 3 NS

IF ANY OF Q. 9-31 IS ANSWERED "YES", PATIENT IS INELIGIBLE. PLEASE ENTER PATIENT <u>SCREENING NUMBER</u> ABOVE AND SIGN FORM BELOW.

32. Did subject sign informed consent form for participation in the study? ..... 1 Yes 2 No 3 NS

33. Is the subject eligible for randomization? ..... 1 Yes 2 No 3 NS

If Yes, complete the following information and call the Perry Point CSPCC to randomize the patient.

34. Enter sum of scores for items 1-24 from the HAM-D (See Form 02) .....

35. To have ADHD based on the DSM-IV screen, patient must meet DSM-IV criteria for both child and adult. Does patient have ADHD (see Forms 03 & 04)? ..... 1 Yes 2 No

THE PERRY POINT CSPCC PROVIDES THE FOLLOWING INFORMATION.

36. Date of randomization .....Mo Day Yr

37. Randomization number ..... (Center - Patient) —

FORM COMPLETED BY _ Date _

SITE INVESTIGATOR'S SIGNATURE _ Date _

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Name Code	Center No.	Patient No.	Week	Date of Assessment
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FORM 02 - HAMILTON DEPRESSION RATING SCALE

INSTRUCTIONS: FOR EACH ITEM, WRITE THE NUMBER IN THE SPACE CORRESPONDING WITH THE "CUE" WHICH BEST CHARACTERIZES THE PARTICIPANT (see Guide for The Hamilton Depression Rating Scale in Operations Manual [Data Management Handbook, Section IV]). This form is to be completed at screening, the first visit of weeks 3, 5 and 7, and at termination.

1. DEPRESSED MOOD (sadness, hopeless, helpless, worthless) ..... _____
   - 0 = Absent
   - 1 = These feeling states indicated only on questioning
   - 2 = These feeling states spontaneously reported verbally
   - 3 = Communicates feeling states nonverbally - i.e., through facial expression, posture, voice, and tendency to weep
   - 4 = Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and nonverbal communication

2. FEELINGS OF GUILT ..... _____
   - 0 = Absent
   - 1 = Self-reproach, feels he has let people down
   - 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - 3 = Present illness is a punishment. Delusions of guilt
   - 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. SUICIDE ..... _____
   - 0 = Absent
   - 1 = Feels life is not worth living
   - 2 = Wishes he were dead or any thoughts of possible death to self
   - 3 = Suicide ideas or gesture
   - 4 = Attempts at suicide *(any serious attempt rates 4)*

4. INSOMNIA EARLY ..... _____
   - 0 = No difficulty falling asleep
   - 1 = Complains of occasional difficulty falling asleep - i.e., more than ½ hour
   - 2 = Complains of nightly difficulty falling asleep

5. INSOMNIA MIDDLE ..... _____
   - 0 = No difficulty
   - 1 = Patient complains of being restless and disturbed during the night
   - 2 = Waking during the night - any getting out of bed rates 2 *(except for purposes of voiding)*

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6. INSOMNIA LATE ..... _____
- 0 = No difficulty
- 1 = Waking in early hours of the morning but goes back to sleep
- 2 = Unable to fall asleep again if gets out of bed

7. WORK AND ACTIVITIES ..... _____
- 0 = No difficulty
- 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
- 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirect in listlessness, indecision and vacillation *(feels he has to push self to work or activities)*
- 3 = Decrease in actual time spent in activities or decrease in productivity. (In hospital, rate 3 if patient does not spend at least three hours a day in activities exclusive of ward chores.)
- 4 = Stopped working because of present illness. (In hospital, rate 4 if patient engages in no activities except ward chores, or if patient fails to perform ward chores unassisted.)

8. RETARDATION (slowness of thought and speech; impaired ability to concentrate; decreased motor activity) ..... _____
- 0 = Normal speech and thought
- 1 = Slight retardation at interview
- 2 = Obvious retardation at interview
- 3 = Interview difficult
- 4 = Complete stupor

9. AGITATION ..... _____
- 0 = None
- 1 = Fidgetiness
- 2 = “Playing with” hands, hair, etc.
- 3 = Moving about, cannot sit still
- 4 = Hand-wringing, nail-biting, hair-pulling, biting of lips

10. ANXIETY PSYCHIC ..... _____
- 0 = No difficulty
- 1 = Subjective tension and irritability
- 2 = Worrying about minor matters
- 3 = Apprehensive attitude apparent in face or speech
- 4 = Fears expressed without questioning

11. ANXIETY SOMATIC ..... _____

0 = Absent	*Physiological concomitants of anxiety, such as:*
1 = Mild	*Gastrointestinal - dry mouth, wind, indigestion, diarrhea, cramps, belching*
2 = Moderate	*Cardiovascular - palpitations, headaches*
3 = Severe	*Respiratory - hyperventilation, sighing*
4 = Incapacitating	*Urinary frequency, sweating*

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12. SOMATIC SYMPTOMS GASTROINTESTINAL ..... _____

0 = None
1 = Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen
2 = Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. SOMATIC SYMPTOMS GENERAL ..... _____

0 = None
1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability
2 = Any clear-cut symptom rates 2

14. GENITAL SYMPTOMS ..... _____

0 = Absent
1 = Mild
2 = Severe

Symptoms such as: Loss of libido, Menstrual disturbances

15. HYPOCHONDRIASIS ..... _____

0 = Not present
1 = Self-absorption (bodily)
2 = Preoccupation with health
3 = Frequent complains, requests for help, etc.
4 = Hypochondriacal delusions

16. LOSS OF WEIGHT ..... _____

0 = No weight loss
1 = Probable weight loss associated with present illness
2 = Definite (according to patient) weight loss

17. INSIGHT ..... _____

0 = Acknowledges being depressed and ill
1 = Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
2 = Denies being ill at all

18. DIURNAL VARIATION (If no variation, mark "0". If variation exists, note whether symptoms are worse in the morning or evening.) ..... _____

0 = No variation (go to Question 19)

1 = Mild ~ Worse in A.M.

2 = Severe ~ Worse in P.M

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19. DEPERSONALIZATION AND DEREALIZATION ..... _____

0 = Absent
1 = Mild *Such as: Feelings of unreality, Nihilistic ideas*
2 = Moderate
3 = Severe
4 = Incapacitating

20. PARANOID SYMPTOMS ..... _____

0 = None
1 = Suspicious
2 = Ideas of reference
3 = Delusions of reference and persecution
4 = Incapacitating

21. OBSESSIONAL AND COMPULSIVE SYMPTOMS ..... _____

0 = Absent
1 = Mild
2 = Severe

22. HELPLESSNESS ..... _____

0 = Not present
1 = Subjective feelings which are elicited only by inquiry
2 = Patient volunteers his helpless feelings
3 = Requires urging, guidance and reassurance to accomplish ward chores or personal hygiene
4 = Requires physical assistance for dress, grooming, eating, bedside tasks or personal hygiene

23. HOPELESSNESS ..... _____

0 = Not present
1 = Intermittently doubts that "things will improve" but can be reassured
2 = Consistently feels "hopeless" but accepts reassurances
3 = Expresses feelings of discouragement, despair, pessimism about future, which cannot be dispelled
4 = Spontaneously and inappropriately perseverates, "I'll never get well" or its equivalent

24. WORTHLESSNESS (ranges from mild loss of esteem, feelings of inferiority, self-depreciation to delusional notions of worthlessness) ..... _____

0 = Not present
1 = Indicates feelings of worthlessness (loss of self -esteem) only on questioning
2 = Spontaneously indicates feelings of worthlessness (loss of self-esteem)
3 = Different from 2 by degree: patients volunteers that he is "no good," "inferior," etc.
4 = Delusional notions of worthless - e.g., "I am a heap of garbage" or its equivalent

Ranges from mild loss of esteem, feelings of inferiority, self-deprecation (loss of self-esteem) to delusional notions of worthlessness.

ENTER SUM OF SCORES FOR ITEMS 1-24 ..... ____ ____

FORM COMPLETED BY _____ Date _____

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Selegiline Transdermal System

Name Code ~~~~ Center No. ~~~ Patient No. ~~~~ Date of Assessment ~~ – ~~ – ~~~~
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FORM 03 - DSM-IV SCREEN FOR ADHD (Child) (Screening Only)

(See Operations Manual [Data Management Handbook, Section IV] for detailed instructions on completing this form.)

INATTENTION

1. Fail to give close attention to details or make careless mistakes in schoolwork or other activities?.....1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

2. Have difficulty sustaining attention in tasks or play activities? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

3. Not listen when you were spoken to directly? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

4. Not follow through on instructions and fail to finish schoolwork or chores? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

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5. Have difficulty organizing tasks and activities? ..... 1___ Yes 2___ No

a. Age ..... ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

6. Avoid, dislike, or were reluctant to engage in task that required sustained mental effort (such as schoolwork)? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

7. Lose things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools)? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

8. Become easily distracted by irrelevant noises or movement? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

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9. Tend to be forgetful in daily activities? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

HYPERACTIVITY

10. Fidget with your hands or feet or squirm in your seat? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

11. Leave your seat in classroom or in other situations in which remaining seated is expected? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

12. Run about or climb excessively in situations in which it was inappropriate? (In adults, may be limited to subjective feelings of restlessness) ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

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13. Have difficulty playing or engaging in leisure activities quietly? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

14. Tend to be "on the go" or act as if you were "driven by a motor"? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

15. Talk excessively? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

IMPULSIVITY

16. Blurt out answers before questions were completed? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

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17. Have difficulty awaiting your turn? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

18. Interrupt or intrude on others (e.g., butt into conversations or games)? ..... 1___ Yes 2___ No

a. Age ___ ___

b. Home ..... 1___ Yes 2___ No

c. School ..... 1___ Yes 2___ No

d. Other, specify _____ ..... 1___ Yes 2___ No

Assessment of Childhood ADHD

19. Are six (or more) of Questions 1 through 9 OR six (or more) of questions 10 through 18 answered YES? ..... 1___ Yes 2___ No

If Yes, complete "a" and "b". If No, patient does not meet criteria for childhood ADHD, skip to Q.20.

a. Were these same 6 or more symptoms (Q.19) present by age twelve? ..... 1___ Yes 2___ No

b. Was at least one symptom present in two (or more) settings (i.e., home, school, other)? ..... 1___ Yes 2___ No

If Q.19, Q.19a and 19b are ALL answered YES, then childhood ADHD is

confirmed. Otherwise, patient does not meet criteria for childhood ADHD.

20. Does patient meet criteria for childhood ADHD? ..... 1___ Yes 2___ No

If Question 20 is YES, Form 04, DSM-IV Screen for ADHD (Adult), must be completed for this patient. If Question 20 is NO, do NOT complete Form 04.

FORM COMPLETED BY _ Date _

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FORM 04 - DSM-IV SCREEN FOR ADHD (Adult) (Screening Only)

(See Operations Manual [Data Management Handbook, Section IV] for detailed instructions on completing this form.)

INATTENTION

1. Fail to give close attention to details or make careless mistakes in schoolwork or other activities? 1___ Yes 2___ No

a. Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning ..... 0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

2.Have difficulty sustaining attention in tasks or play activities? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

3.Not listen when you were spoken to directly? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

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4.Not follow through on instructions and fail to finish schoolwork or chores? ..... 1___ Yes 2___ No
a.Home ..... 1___ Yes 2___ No
b.Work ..... 1___ Yes 2___ No
c.Other, specify _____ ..... 1___ Yes 2___ No
d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely
e.Remission ..... 1___ Yes 2___ No

5.Have difficulty organizing tasks and activities? ..... 1___ Yes 2___ No
a.Home ..... 1___ Yes 2___ No
b.Work ..... 1___ Yes 2___ No
c.Other, specify _____ ..... 1___ Yes 2___ No
d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely
e.Remission ..... 1___ Yes 2___ No

6. Avoid, dislike, or were reluctant to engage in task that required sustained mental effort (such as schoolwork)? ..... 1___ Yes 2___ No
a.Home ..... 1___ Yes 2___ No
b.Work ..... 1___ Yes 2___ No
c.Other, specify _____ ..... 1___ Yes 2___ No
d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely
e.Remission ..... 1___ Yes 2___ No

7. Lose things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools)? ..... 1___ Yes 2___ No
a.Home ..... 1___ Yes 2___ No
b.Work ..... 1___ Yes 2___ No
c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

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8.Become easily distracted by irrelevant noises or movement? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

9.Tend to be forgetful in daily activities? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning ..... 0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

HYPERACTIVITY

10.Fidget with your hands or feet or squirm in your seat? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

11. Leave your seat in classroom or in other situations in which remaining seated is expected? 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

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12. Run about or climb excessively in situations in which it was inappropriate? (May be limited to subjective feelings of restlessness) 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning ..... 0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

13.Have difficulty playing or engaging in leisure activities quietly? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

14.Tend to be “on the go” or act as if you were “driven by a motor”? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

15.Talk excessively? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

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IMPULSIVITY

16.Blurt out answers before questions were completed? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

17.Have difficulty awaiting your turn? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning ..... 0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

18.Interrupt or intrude on others (e.g., butt into conversations or games)? ..... 1___ Yes 2___ No

a.Home ..... 1___ Yes 2___ No

b.Work ..... 1___ Yes 2___ No

c.Other, specify _____ ..... 1___ Yes 2___ No

d.Functioning .....0___ Not at all 1___ Mildly 2___ Moderately 3___ Severely

e.Remission ..... 1___ Yes 2___ No

Assessment of Current ADHD - To meet the criteria for assessment of current ADHD, patient must report that: s/he experiences three (or more) inattention items (questions 1 through 9) OR four (or more) hyperactivity-impulsivity items (questions 10 through 18) OR six (or more) total items (questions 1 through 18) EACH OF WHICH effects his/her functioning moderately (2) or severely (3).

19.Does patient meet criteria for current ADHD? ..... 1___ Yes 2___ No

FORM COMPLETED BY _ Date _

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FORM 05 - INFECTIOUS DISEASE (Screening Only)

	VALUE 1=Positive 2=Negative 3=Indeterminate 9=Not done	EVALUATION 1=Excludes 2=Does not exclude 9=Not done	COMMENTS Provide comments for any assessment that is positive, indeterminate, or not done.
1. Hepatitis B Surface Antigen (Hbs Ag)	_____	_____	_____
2. Hepatitis B Surface Antibody (Anti-HBs)	_____	_____	_____
3. Hepatitis B Core Antibody (Anti-HBc)	_____	_____	_____
4. Hepatitis C Virus Antibody (HCV Ab)	_____	_____	_____
5. PPD	_____	_____	_____

A. Date of PPD test: Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

If PPD is positive or not done, a chest x-ray is required.

B. Date of chest x-ray: Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

C. Chest x-ray result: 1 ____ Normal 2____ Abnormal, study entry OK 3____ Abnormal, excludes from study entry

6. RPR: 1 _____ Reactive 2 _____ Nonreactive

A. If reactive, FTA-abs (or MHA-TP, or TP-PA) test is: 1 _____ Positive (refer for treatment) 2 _____ Negative

FORM COMPLETED BY _ Date _

PHYSICIAN'S SIGNATURE _ Date _

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code ~~~~ Center No. ~~~ Patient No. ~~~~ Date of Assessment ~~ – ~~ – ~~~~
Month Day Year

FORM 06 - MEDICAL HISTORY (Screening Only)

Medical Conditions:	A. Yes, Excludes	B. Yes, Not Excluded	C. No history Of	D. Explain or Describe (Print CLEARLY) (Required if "A" or "B" is checked)
1. Allergies, drug	____	____	____	_____
2. Allergies, other	____	____	____	_____
3. Sensitivity to study med	____	____	____	_____
4. HEENT Disorder	____	____	____	_____
5. Cardiovascular Disorder	____	____	____	_____
6. Renal Disorder	____	____	____	_____
7. Hepatic Disorder	____	____	____	_____
8. Pulmonary Disorder, asthma	____	____	____	_____
9. Pulmonary Disorder, other	____	____	____	_____
10. Gastrointestinal Disorder	____	____	____	_____
11. Musculoskeletal Disorder	____	____	____	_____
12. Neurologic Disorder:				
A. Neuroleptic Malignant Syn.	____	____	____	_____
B. Other	____	____	____	_____
13. Psychiatric Disorder	____	____	____	_____
14. Dermatologic Disorder	____	____	____	_____
15. Metabolic Disorder	____	____	____	_____
16. Hematologic Disorder	____	____	____	_____
17. Endocrine Disorder	____	____	____	_____
18. Genitourinary Disorder	____	____	____	_____
19. Reproductive System	____	____	____	_____
20. Infectious Disease	____	____	____	_____
21. Other _____	____	____	____	_____
22. Other _____	____	____	____	_____

Name Code	Center No.	Patient No.	Date of Assessment
~ ~ ~ ~	~ ~ ~	~ ~ ~ ~	~ ~ – ~ ~ – ~ ~ ~ ~
			Month Day Year

23. **Has patient had any major surgery**? ..... 1___ Yes 2___ No

If Yes, List MAJOR SURGERIES below. If No, skip to Q. 24.

1.	TYPE OF SURGERY	DATE OF SURGERY (Month/Year)	2. IS SURGERY RELEVANT TO STUDY? Yes, Excludes	Yes, Does Not Exclude	No
A.	_____	__ __ / __ __ __ __	____	____	____
B.	_____	__ __ / __ __ __ __	____	____	____
C.	_____	__ __ / __ __ __ __	____	____	____
D.	_____	__ __ / __ __ __ __	____	____	____
E.	_____	__ __ / __ __ __ __	____	____	____

SMOKING HISTORY

24. **Do you smoke cigarettes now (i.e., within past week)**? ..... 1___ Yes 2___ No, skip to Q. 25

If Yes:

A. Number of YEARS smoked ..... ___ ___

B. Average NUMBER of cigarettes/day ..... ___ ___

25. **Have you ever smoked cigarettes for at least one year?** ..... 1___ Yes 2___ No, skip to Q. 26

If Yes:

A. Number of YEARS smoked ..... ___ ___

B. Average NUMBER of cigarettes/day ..... ___ ___

26 **Do you use other tobacco products now (i.e., within past week)?**..... 1___ Yes 2___ No, skip to Q. 27

	If Yes:	1. CIGAR	2. CHEW	3. SNUFF	4. PIPE
A.	Currently using?	1__yes 2__no	1__yes 2__no	1__yes 2__no	1__yes 2__no
B.	Number of years used:	__ __ years	__ __ years	__ __ years	__ __ years
C.	Average number of times used/day:	__ __	__ __	__ __	__ __

Name Code	Center No.	Patient No.	Date of Assessment
~ ~ ~ ~	~ ~ ~	~ ~ ~ ~	~ ~ – ~ ~ – ~ ~ ~ ~
			Month Day Year

27. **Have you ever used other tobacco products for at least one year?**..... 1___ Yes 2___ No

	If Yes:	1. CIGAR	2. CHEW	3. SNUFF	4. PIPE
A.	Currently using?	1__yes 2__no	1__yes 2__no	1__yes 2__no	1__yes 2__no
B.	Number of years used:	__ __ years	__ __ years	__ __ years	__ __ years
C.	Average number of times used/day:	__ __	__ __	__ __	__ __

FORM COMPLETED BY _ Date _

PHYSICIAN'S SIGNATURE _ Date _

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code ~~~~ Center No. ~~~ Patient No. ~~~~ Date of Assessment ~~ - ~~ - ~~~~
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FORM 07 - PRIOR MEDICATION FORM

Complete this form on the day patient signs the Informed Consent. List all medications taken by the patient for the PAST 60 DAYS. Update on Treatment Day 1 (day 1st study patch applied) prior to patch application to capture medications taken during the screening period.

A GENERIC NAME OF MEDICATION	B PURPOSE/INDICATION	C - ROUTE 1=Oral 2=Nasal 3=Intravenous 4=Inhalation 5=Topical transdermal 6=Intramuscular 7=Sublingual 8=Subcutaneous 9=Other	D DOSE	E - UNITS 01=Capsule/Tablet 02=Drop 03=Milligram 04=Milliliter 05=Puff 06=Spray/squirt 07=Tablespoon 08=Teaspoon 09=Unknown 10=Other	F FREQUENCY 1=<1/DAY 2=1-4 /DAY 3=PRN 4=>4/DAY	G MEDICATION START DATE (Mo/Day/Yr) *circle "c" if continuing*	H MEDICATION STOP DATE (Mo/Day/Yr)

1.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _
2.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _

3.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _
4.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _

5.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _
6.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _

7.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _
8.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _

9.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _
10.		_____	_ _ _ _ _ . _ _ _ _	_ _ _ _	_____	_ _ _/_ _ _/_ _ _ _ _	c	_ _ _/_ _ _/_ _ _ _ _

FORM COMPLETED BY_____ Date _____

PHYSICIAN'S SIGNATURE _____ Date _____

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code	Center No.	Patient No.	Week	Date of Interview
~ ~ ~ ~	~ ~ ~	~ ~ ~ ~ ~	~	~ ~ - ~ ~ - ~ ~ ~ ~
				Month Day Year

FORM 08 - ADDICTION SEVERITY INDEX (ASI) (Fifth Edition) (Modified)

INSTRUCTIONS

1. Leave No Blanks-Where appropriate code items:
   X = question not answered
   N = question not applicable
   Use only one character per item.

2. Item numbers circled are to be asked at last visit. Items with an asterisk are cumulative and should be rephrased at last visit (see ASI Manual in Operations Manual).

3. Space is provided after sections for additional comments.

SEVERITY RATINGS

The severity ratings are interviewer estimates of the patient's need for additional treatment in each area. The scales range from 0 (no treatment necessary) to 9 (treatment needed to intervene in life-threatening situation). Each rating is based upon the patient's history of problem symptoms, present condition and subjective assessment of his treatment needs in a given area. For a detailed description of severity ratings' derivation procedures and conventions, see ASI Manual (in Operations Manual).
Note: These severity ratings are optional.

SUMMARY OF PATIENT'S RATING SCALE

0 = Not at all
1 = Slightly
2 = Moderately
3 = Considerably
4 = Extremely

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GENERAL INFORMATION

G14. How long have you lived at your current address? ~~ ~~ YRS. ~~ ~~ MOS.

G15. Is this residence owned by you or your family? ~

0 = No 1 = Yes

G16. DATE OF BIRTH (mo/day/yr) ~~ ~~ ~~ ~~

~~ ~~ ~~ ~~

G17. RACE ~

1=White (not of Hispanic Origin)
2=Black (not of Hispanic Origin)
3=American Indian
4=Alaskan Native
5=Asian or Pacific Islander
6=Hispanic - Mexican
7=Hispanic - Puerto Rican
8=Hispanic - Cuban
9=Other Hispanic

G18. RELIGIOUS PREFERENCE ~

1=Protestant 4=Islamic
2=Catholic 5=Other
3=Jewish 6=None

F G19 Have you been in a controlled environment in the past 30 days? ~

1=No
2=Jail
3=Alcohol or Drug Treatment
4=Medical Treatment
5=Psychiatric
6=Other _____

F G20 How many days? ~~

This form should be completed at:
Baseline
Week 5 (first visit of week)*
Termination*

*Answer only circled item numbers at week 5 and termination.

NOTE:
Some questions on this form (demographics) have been eliminated because this information is being asked on other study forms.

CS 1019 - FORM 08 Name Code ~~~~ Center No. ~~~ Week ~ Patient No. ~~~~

FORM COMPLETED BY _ Date _____

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code	Center No.	Patient No.	Week	Date of Assessment
~~	~~~	~~~~	~	~~ – ~~ – ~~~~
				Month Day Year

FORM 09 - PHYSICAL EXAM/SCID
(To be completed at Screening and Termination)

NOTE: If Screening Physical Exam, update Q.17 on Treatment Day 1 (day 1st patch applied) prior to patch application to capture any new problems since last assessed.

1. Height (complete at Screening Only)..... ___ ___ . ___ inches

	A. RESULTS OF EXAM 1=Abnormal, excludes 2=Abnormal, does not exclude 3=Normal 9=Not done	**B. PROVIDE DETAILS ON EACH ABNORMALITY BELOW.**
2. HEENT (incl. thyroid/neck)	_____	_____
3. Cardiovascular.....	_____	_____
4. Lungs	_____	_____
5. Abdomen (incl. liver, spleen)	_____	_____
6. Extremities	_____	_____
7. Skin	_____	_____
8. Neuropsychiatric:		
A. Mental Status	_____	_____
B. Sensory/Motor	_____	_____
9. Lymph Nodes	_____	_____
10. Musculoskeletal	_____	_____
11. General Appearance.....	_____	_____
12.Other, specify _____	_____	
_____		
13. Other, specify _____	_____.....	
_____		
14. Other, specify _____	_____	_____
15. Other, specify _____	_____	_____

CS 1019 - FORM 09 (Page 2 of 3)

Name Code	Center No.	Patient No.	Week	Date of Assessment
~~	~~~	~~~~	~	~~ - ~~ - ~~~~
				Month Day Year

16. Does the patient have any ongoing medical problems (chronic) other than his/her cocaine addiction? ..... 1___ Yes 2___ No

If Yes, list these problems below:

1. NATURE OF PROBLEM	DATE OF ONSET (Mo/Day/Yr)	2. SEVERITY 1=Mild 2=Moderate 3=Severe
A. _____	__ __-__ __-__ __ __ __	_____
B. _____	__ __-__ __-__ __ __ __	_____
C. _____	__ __-__ __-__ __ __ __	_____
D. _____	__ __-__ __-__ __ __ __	_____
E. _____	__ __-__ __-__ __ __ __	_____
F. _____	__ __-__ __-__ __ __ __	_____

17. Has the patient had any problems in the past 7 days or since last assessment? ..... 1___ Yes 2___ No

If Yes, please describe each problem, illness or clinically significant abnormal lab value and associated information below.

Severity Codes	**Outcome Codes**
1=Mild 2=Moderate 3=Severe	1=Resolved; No Sequelae 2=Not yet resolved 3=Resulted in chronic condition, severe and/or permanent disability 4=Unknown

Nature of Problem, Illness, or Abnormal Lab Value	Date of Onset (mo/day/yr)	Date of Resolution (mo/day/yr)	Severity Code	Outcome Code
A.	__ __ /__ __ /__ __ __ __	__ __ /__ __ /__ __ __ __		
B.	__ __ /__ __ /__ __ __ __	__ __ /__ __ /__ __ __ __		
C.	__ __ /__ __ /__ __ __ __	__ __ /__ __ /__ __ __ __		
D.	__ __ /__ __ /__ __ __ __	__ __ /__ __ /__ __ __ __		
E.	__ __ /__ __ /__ __ __ __	__ __ /__ __ /__ __ __ __		

F.	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		

Name Code ~ ~ ~ ~ Center No. ~ ~ ~ Patient No. ~ ~ ~ ~ Week ~ Date of Assessment ~ ~ – ~ ~ – ~ ~ ~ ~

Month Day Year

COMPLETE THE SCID AT SCREENING ONLY

18. **SCID - Summary of Axis I Diagnoses**. Indicate the three, four, or five-digit DSM-IV diagnostic code for all Axis I diagnoses, followed by the diagnostic description. After the "/", use the sixth digit to indicate the following specifiers: 0: "current, severity not specified," 1: "current, mild," 2: "current, moderate," 3: "current, severe," (NOTE: no number "4"), 5: "in partial remission," 6: "in full remission." When the specifier information is already included in the fifth digit of the code, repeat this information as the sixth digit.

1) ___ ___ ___ . ___ ___ / ___ _____
2) ___ ___ ___ . ___ ___ / ___ _____
3) ___ ___ ___ . ___ ___ / ___ _____
4) ___ ___ ___ . ___ ___ / ___ _____
5) ___ ___ ___ . ___ ___ / ___ _____
6) ___ ___ ___ . ___ ___ / ___ _____
7) ___ ___ ___ . ___ ___ / ___ _____
8) ___ ___ ___ . ___ ___ / ___ _____
9) ___ ___ ___ . ___ ___ / ___ _____
10) ___ ___ ___ . ___ ___ / ___ _____

FORM COMPLETED BY _ Date _

PHYSICIAN'S SIGNATURE _ Date _

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code ☐☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐☐ Week ☐ Date of Assessment ☐☐-☐☐-☐☐☐☐

Month Day Year

FORM 10 - BIRTH CONTROL/PREGNANCY ASSESSMENT (Women Only)

1.What method of birth control is participant currently using? ..... __ __

01 = Oral contraceptive

02 = Barrier (diaphragm or condom plus spermicide)

03 = Levonorgestrel implant (Norplant)

04 = Intrauterine Progesterone Contraceptive system (IUD)

05 = Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)

06 = Complete abstinence

07 = Hysterectomy, record date of procedure: Mo __ __ Yr __ __ __ __

08 = Tubal ligation, record date of procedure: Mo __ __ Yr __ __ __ __

09 = Post-menopausal, record date of last menstrual period: Mo __ __ Yr __ __ __ __

10 = Other, specify _____

2.Result of pregnancy test ..... 1___ Positive 2___ Negative

1.Date specimen collected ..... Mo __ __ Day __ __ Yr __ __ __ __

2.Type of specimen ..... 1___ Urine 2___ Serum

FORM COMPLETED BY _ Date _

PHYSICIAN'S SIGNATURE _ Date _

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code	Center No.	Patient No.	Week	Date of ECG
~~	~~~	~~~~	~	~~ – ~~ – ~~~~
				Month Day Year

FORM 11 - ELECTROCARDIOGRAM RESULTS (ECG)

(To be completed at Screening and Termination)

1. ECG overall results were: 1=Normal, 2=Abnormal ..... _____

2. If ECG is abnormal, CHECK ALL that apply below:

A	9	Increased QRS voltage	L	9	Sinus tachycardia
B	9	Qt_c prolongation	M	9	Sinus bradycardia
C	9	Left ventricular hypertrophy	N	9	Supraventricular premature beat
D	9	Right ventricular hypertrophy	O	9	Ventricular premature beat
E	9	Acute infarction	P	9	Supraventricular tachycardia
F	9	Subacute infarction	Q	9	Ventricular tachycardia
G	9	Old infarction	R	9	1st degree A-V block
H	9	Myocardial ischemia	S	9	2nd degree A-V block
I	9	Symmetrical t-wave inversions	T	9	3rd degree A-V block
J	9	Poor R-wave progression	U	9	Other, specify _____
K	9	Other nonspecific ST/T	V	9	Other, specify _____

3. Ventricular rate (bpm) ..... ___ ___ ___

4. PR (ms) ..... ___ ___ ___

5. QRS (ms) ..... ___ ___ ___

6. QT_c (ms) ..... ___ ___ ___

7. Read By: _____ Date Read: Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

COMPLETE AT SCREENING ONLY:

8. Do any of the abnormalities preclude safe entry into the study? .....1___Yes 2___No

If Yes, LIST IN ORDER OF IMPORTANCE, the letter indicator(s) from Question 2 above that are exclusionary ..... ___ ___ ___ ___ ___

FORM COMPLETED BY _ Date _
PHYSICIAN'S SIGNATURE _ Date _
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VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code	Center No.	Patient No.	Week	Date of Assessment
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FORM 12 - COCAINE CLINICAL GLOBAL IMPRESSION SCALE SELF REPORT (CGI-S)

1. Cocaine Global Severity

At this time, overall, how would you rate yourself for cocaine use and cocaine related problems? ..... _____

1 = No problems
2 = Borderline problems
3 = Mild problems
4 = Moderate problems
5 = Marked problems
6 = Severe symptoms
7 = Among the most extreme symptoms

If this is a baseline visit, STOP here. Do not answer Question 2.

2. Global Improvement of Cocaine Dependence

How would you rate yourself for changes in cocaine use and cocaine related problems since the beginning of this study? ..... _____

1 = Very much improved
2 = Much improved
3 = Minimally improved
4 = No change
5 = Minimally worse
6 = Much worse
7 = Very much worse

FORM COMPLETED BY _ Date _____

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code	Center No.	Patient No.	Week	Date of Assessment
~~	~~~	~~~~	~	~~ - ~~ - ~~~~
				Month Day Year

FORM 13 - COCAINE CLINICAL GLOBAL IMPRESSION SCALE OBSERVER (CGI-O)

PART A. Please rate the Current Severity of the eight specific problem areas below. See "table of descriptive anchors for specific Cocaine Dependence Problems" in the instructions. Indicate one answer for each question.

1. Reported Cocaine Use:
.....(frequency and amount of cocaine use)
..... 1___ 2___ 3___ 4___ 5___ 6___ 7___

2. Cocaine Seeking:
(craving for cocaine, effort to stop, and drug
..... seeking behavior)
..... 1___ 2___ 3___ 4___ 5___ 6___ 7___

3. Reported Use of Other Drugs:
(frequency and amount of non-cocaine drug/
.....alcohol use)
..... 1___ 2___ 3___ 4___ 5___ 6___ 7___

4. Observable Psychiatric Symptoms:
(orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance,
..... paranoia, suspiciousness)
..... 1___ 2___ 3___ 4___ 5___ 6___ 7___

5. Reported Psychiatric Symptoms:
(mood disturbance, depression, anxiety, inner restlessness, covert anger, somatic symptoms, energy level, motivation, sleep, appetite, libido,
.....anhedonia, paranoia, suspiciousness)
..... 1___ 2___ 3___ 4___ 5___ 6___ 7___

6. Physical/Medical Problems:
(those that have emerged or gotten worse after
.....drug use)
..... 1___ 2___ 3___ 4___ 5___ 6___ 7___

7. Maladaptive Coping in the Family/Social area:
.....(movement away from healthy relationship)
..... 1___ 2___ 3___ 4___ 5___ 6___ 7___

8. Maladaptive Coping in Other areas:
(e.g., employment, legal, housing, etc. movement
.....away from problem solving in those areas)
..... 1___ 2___ 3___ 4___ 5___ 6___ 7___

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CSP #1019 - Form 13 (Page 2 of 2)

Name Code	Center No.	Patient No.	Week	Date of Assessment
~ ~ ~ ~	~ ~ ~	~ ~ ~ ~	~	~ ~ - ~ ~ - ~ ~ ~ ~
				Month Day Year

PART B.

9. Global Severity of Cocaine Dependence ..... _____

Considering your total clinical experience with the cocaine population, how severe are his/her cocaine dependence symptoms at this time?

1 = Normal no symptoms
2 = Borderline symptoms
3 = Mild symptoms
4 = Moderate symptoms
5 = Marked symptoms
6 = Severe symptoms
7 = Among the most extreme symptoms

<u>If this is a baseline visit, STOP here.</u>

10. Global Improvement of Cocaine Dependence ..... _____

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her status at randomization, how much has s/he changed?

1 = Very much improved
2 = Much improved
3 = Minimally improved
4 = No change
5 = Minimally worse
6 = Much worse
7 = Very much worse

FORM COMPLETED BY _ Date _____

PHYSICIAN'S SIGNATURE _ Date _____

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code ~~~~ Center No. ~~~ Patient No. ~~~~ Week ~~ Date of Assessment ~~ – ~~ – ~~~~
Month Day Year

FORM 14 - SUBSTANCE USE REPORT (SUR)

1. This form is being completed for date: *(do not answer at follow-up visit)*..... Mo __ __ Day __ __ Yr __ __ __ __

2. Any substance use on this date *(or past 30 days if follow-up visit)*? ..... 1 Yes (continue) 2 No (stop, form is complete)
Complete a line below for each unique route employed to use a substance (e.g., "nasal" and "inhaled" for cocaine require separate lines). If this is the follow-up visit, record substance use for the past 30 days.

*Nicotine Codes (Q.7): 1=Cigarettes, 2=Sticks of gum/nicorette, 3=Patch, 4=Cigars, 5=Other †Substance Codes (Q.8-11): 1=Other stimulants (amph, crystal meth, etc), 2=Hallucinogens (PCP, LSD, ecstacy, etc), 3=Inhalants (glue, ethyl chl, etc.), 4=Sedative hypn/anxiolytics (valium, seconal, etc.), 5=Other	A. TOTAL AMOUNT	B. ROUTE 1=Oral 2=Nasal 3=Intravenous 4=Inhalation 5=Topical Transdermal 6=Intramuscular 7=Sublingual 8=Subcutaneous 9=Other
3A. Cocaine		_____
3B. Cocaine		_____
3C. Cocaine		_____
4A. Beer (record the # of standard 12 oz beer drinks)	___ ___ ___ ___	One"standard drink" is equal to: - 12 oz. of beer (4-5% EtOH) - 4 oz. of wine (10-12% EtOH) - 2.5 oz. of fortified wine (16-18% EtOH) - 1 oz. of hard liquor (86-100 proof, 43-50% EtOH)
4B. Wine (record the # of standard 4 oz. wine drinks)	___ ___ ___ ___	
4C. Hard liquor (record the # of standard 1 oz. liquor drinks)	___ ___ ___ ___	
5. Marijuana		_____
6A. Opioids: specify _____		_____
6B. Opioids: specify _____		_____
7A. Nicotine, specify (Code ____ *) _____	___ ___ ___ ___	_____
7B. Nicotine, specify (Code ____ *) _____	___ ___ ___ ___	_____
8. Other, specify (Code ____ †) _____		_____
9. Other, specify (Code ____ †) _____		_____
10. Other, specify (Code ____ †) _____		_____
11. Other, specify (Code ____ †) _____		_____

FORM COMPLETED BY _ Date _____

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code ~~~~ Center No. ~~~ Patient No. ~~~~ Week ~ Date of Assessment ~~ – ~~ – ~~~~
Month Day Year

FORM 15 - CLINICAL LABORATORY REPORT

TO BE COMPLETED AT SCREENING, 1st VISIT OF WEEK 4 AND TERMINATION. Contact Medical Monitor or Principal Investigator at NIDA if any lab value is clinically significantly abnormal as listed in the Protocol (see Appendix I).

BLOOD CHEMISTRY	**A.Value***	**B. Evaluation**** 1=Abnormal, excludes 2=Abnormal, does not exclude 3=Normal 9=Not done	**C. Comments** - Provide comments for any abnormal value.
1. Sodium (mEq/L)	___ ___ ___	_____	
2. Potassium (mEq/L)	___ . ___	_____	
3. Chloride (mEq/L)	___ ___ ___	_____	
4. CO2 (mEq/L)	___ ___	_____	
5. Glucose (mg/dL)	___ ___ ___	_____	
6. Creatinine (mg/dL)	___ . ___	_____	
7. Albumin (g/dL)	___ ___ . ___	_____	
8. Total protein (g/dL)	___ ___ . ___	_____	
9. Calcium (mg/dL)	___ ___ . ___	_____	
10. Cholesterol (mg/dL)	___ ___ ___	_____	
11. Triglycerides (mg/dL)	___ ___ ___	_____	
12. SGOT/AST (U/L)	___ ___ ___ ___	_____	
13. SGPT/ALT (U/L)	___ ___ ___ ___	_____	
14. GGT (U/L)	___ ___ ___ ___	_____	
15. Total bilirubin (mg/dL)	___ ___ . ___	_____	
16. LDH (U/L)	___ ___ ___	_____	
17. Alkaline phosphatase (U/L)	___ ___ ___	_____	
18. BUN (mg/dL)	___ ___ ___	_____	
19. Uric acid (mg/dL)	___ ___ . ___	_____	
20.Other_____	___ ___ ___ ___ . ___	_____	
21.Other_____	___ ___ ___ ___ . ___	_____	
22.Other_____	___ ___ ___ ___ . ___	_____	

*Conversion Chart for lab values provided in Section X of Operations Manual if needed.
**See Clinically Significantly Abnormal Laboratory Values in Protocol (Appendix I)/Operations Manual.

Name Code Center No. Patient No. Week Date of Assessment

~~~~ ~~~ ~~~~ ~ ~~ - ~~ - ~~~~

Month Day Year

CBC	A.Value	B. Evaluation** 1=Abnormal, excludes 2=Abnormal, does not exclude 3=Normal 9=Not done	C. Comments - Provide comments for any abnormal value.
23. Hemoglobin (g/dL)	___ ___ . ___	_____	
24. Hematocrit (%)	___ ___ . ___	_____	
25. RBC (M/mm^3)	___ ___ . ___	_____	
26. Platelet count (K/mm^3)	___ ___ ___	_____	
27. WBC (K/mm^3)	___ ___ . ___	_____	
28. Neutrophils (%)	___ ___ . ___	_____	
29. Lymphocytes (%)	___ ___ . ___	_____	
30. Monocytes (%)	___ ___ . ___	_____	
31. Eosinophils (%)	___ ___ . ___	_____	
32. Basophils (%)	___ ___ . ___	_____	
URINALYSIS			
33. Specific gravity	___ . ___ ___ ___	_____	
34. pH	___ ___ . ___	_____	
35. Glucose	**1___Neg 2___Trace 3___Present**	_____	
36. Protein	**1___Neg 2___Trace 3___Present**	_____	
37. Ketones	**1___Absent 2___Trace 3___Present**	_____	
38. Occult Blood	**1___Absent 2___Present**	_____	
CODING FOR Q. 39-41: **None (1-5) Few (6-10) Mod (>10) Heavy**			
39. WBC	**1___ 2___ 3___ 4___**	_____	
40. RBC	**1___ 2___ 3___ 4___**	_____	
41. Epithelial Cells	**1___ 2___ 3___ 4___**	_____	

FORM COMPLETED BY _____ Date _____

PHYSICIAN'S SIGNATURE _____ Date _____
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VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code	Center No.	Patient No.	Week	Date Blood Drawn
~ ~ ~ ~	~ ~ ~	~ ~ ~ ~	~	~~ – ~~ – ~~~~
				Month Day Year

FORM 16 - SELEGILINE BLOOD LEVEL FORM

1.Time of blood draw (24 hr clock) ..... ___ ___ : ___ ___

2. Last patch application (DO NOT COMPLETE AT BASELINE):

A.Time (24 hr clock) ..... ___ ___ : ___ ___

B.Date Mo ___ ___ Day ___ ___ Year ___ ___ ___ ___

FORM COMPLETED BY _____ Date _____

VA/NIDA STUDY 1019

Selegiline Transdermal System

Name Code	Center No.	Patient No.	Week	Date of Assessment
~ ~ ~ ~	~ ~ ~	~ ~ ~ ~	~	~ ~ – ~ ~ – ~ ~ ~ ~
				Month Day Year

FORM 17 - RISK ASSESSMENT BATTERY

___ Check if asked by interviewer

Interviewer's Name _____ Date

_____

Please read each of the following questions very carefully. As you will see, many of these questions are very personal. We understand this and have taken great care to protect the privacy of your answers.

It is very important that you answer EVERY question honestly. In fact, it's better not to answer a question at all than to tell us something that is not accurate or true. Some questions may not seem to have an answer that is true for you. When this happens, you should simply choose the answer that is most right. Don't spend too much time on any one question. Remember, always ask for help if you're unsure about what to do.

Thank you for your time and cooperation.

Name Code Center No. Patient No. Week Date of Assessment

~~~~ ~~~ ~~~~ ~ ~~ – ~~ – ~~~~

Month Day Year

A. PAST MONTH DRUG AND ALCOHOL USE:

Please **CIRCLE** the most correct response.

1. In the past month, how often have you injected cocaine and heroin together (Speedball)?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

2. In the past month, how often have you injected heroin (not mixed)?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

3. In the past month, how often have you snorted heroin (not mixed)?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

4. In the past month, how often have you smoked heroin?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

5. In the past month, how often have you injected cocaine (not mixed)?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday
~~~~

Name Code Center No. Patient No. Week Date of Assessment

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Month Day Year

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6. In the past month, how often have you <u>snorted</u> cocaine (not mixed)?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

7. In the past month, how often have you <u>smoked</u> crack, rock, or freebase cocaine?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

8. In the past month, how often have you injected amphetamines, meth, speed, crank or crystal?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

9. In the past month, how often have you snorted amphetamines, meth, speed, crank or crystal?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

10. In the past month, how often have you smoked amphetamines, meth, speed, crank or crystal?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday
~~~~

Name Code　　Center No.　　Patient No.　　Week　　Date of Assessment

~ ~ ~ ~　　~ ~ ~　　~ ~ ~ ~　　~　　~ ~ – ~ ~ – ~ ~ ~ ~

Month　Day　Year

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11. In the past month, how often have you used benzodiazepines (benzos, benzies) such as Xanax, Valium, Klonipin or Ativan?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

12. In the past month, how often have you taken painkillers - pills such as Percodan, Percocet, Vicodin, Demerol, Dilaudid, Darvon, Darvocet or syrup (Codeine)?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

    A. Which types of painkillers did you use? ________________________________

13. In the past month, how often have you injected Dilaudid?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

14. In the past month, how often have you used acid, LSD, or other hallucinogens?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

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Name Code	Center No.	Patient No.	Week	Date of Assessment
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				Month Day Year

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15. In the past month, how often have you used marijuana?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

16. In the past month, how often have you used beer, wine, or liquor?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

B. NEEDLE USE:

17. In the past month, have you injected drugs?
    0. NO
    1. YES

18. In the past month, have you shared needles or works?
    0. NO or I have not shot up in the past month
    1. YES

19. With how many different people did you share needles in the past month?
    0. 0 or I have not shot up in the past month
    1. 1 other person
    2. 2 or 3 different people
    3. 4 or more different people

Name Code	Center No.	Patient No.	Week	Date of Assessment
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				Month Day Year

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20. In the past month, how often have <u>you</u> used a needle after someone (with or without cleaning)?
    0. Never or I have not shot up or shared in the past month
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

21. In the past month, how often have <u>others</u> used after you (with or without cleaning)?
    0. Never or I have not shot up or shared in the past month
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

22. In the past month, how often have you shared needles with someone you knew (or later found out) had AIDS or was positive for HIV, the AIDS virus?
    0. Never or I have not shot up or shared in the past month
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

23. Where did you get your needles during the past month?
    (Circle all that apply)
    0. I have not shot up in the past month
    1. From a diabetic
    2. On the street
    3. Drugstore
    4. Shooting gallery or other place where users go to shoot up
    5. Needle Exchange Program
    6. Other, specify_____

---

24. In the past month, how often have you been to a shooting gallery/house or other place where users go to shoot-up?
    0. Never
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

25. In the past month, how often have you been to a Crack House or other place where people go to smoke crack?
    0. Never
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

26. Which statement best describes the way you cleaned your needles during the past month? (Please choose **one)**
    0. I have not shot up in the past month
    1. I always use new needles
    2. I always clean my needle just before I shoot up
    3. After I shoot up, I always clean my needle
    4. Sometimes I clean my needle, sometimes I don't
    5. I never clean my needle

Name Code	Center No.	Patient No.	Week	Date of Assessment
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				Month Day Year

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27. If you have cleaned your needles and works in the past month, how did you clean them? (Circle all that apply)
    0. I have not shot up in the past month
    1. Soap and water or water only
    2. Alcohol
    3. Bleach
    4. Boiling water
    5. Other, specify_____
    6. I did not clean my needles in the past month
    7. I ALWAYS used new needles in the past month

28. In the past month, how often have you shared rinse water?
    0. Never or I have not shot up in the past month
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

29. In the past month, how often have you shared a cooker?
    0. Never or I have not shot up in the past month
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

30. In the past month, how often have you shared a cotton?
    0. Never or I have not shot up in the past month
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

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31. In the past month, how often have you divided or shared drugs with others by using one syringe (yours or someone else's) to squirt or load the drugs into the other syringe(s) (backloading, for example)?
    0. Never or I have not shot up in the past month
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

C. SEXUAL PRACTICES

32. How would you describe yourself?
    1. Straight
    2. Gay or Homosexual
    3. Bisexual

Please note: For the following questions, ***sex*** *means any* ***vaginal intercourse, anal intercourse*** *(in the butt)* ***or oral sex*** *(blowjobs, for example).*

33. With how many men have you had sex in the past month?
    0. 0 men
    1. 1 man
    2. 2 or 3 men
    3. 4 or more men

34. With how many women have you had sex in the past month?
    0. 0 women
    1. 1 woman
    2. 2 or 3 women
    3. 4 or more women

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35. In the past month, how often have you had sex so you could get drugs?
    0. Never
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

36. In the past month, how often have you given drugs to someone so you could have sex with them?
    0. Never
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

37. In the past month, how often were you paid money to have sex with someone?
    0. Never
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

38. In the past month, how often did you give money to someone so you could have sex with them?
    0. Never
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

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				Month Day Year

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39. In the past month, how often have you had sex with someone you knew (or later found out) had AIDS or was positive for HIV, the AIDS virus?
    0. Never
    1. A few times (1 or 2 times)
    2. About once a week (3 or 4 times)
    3. More than once a week (5 or more times)

40. In the past month, how often did you use condoms when you had sex?
    0. I have not had sex in the past month
    1. All the time
    2. Most of the time
    3. Some of the time
    4. None of the time

D. CONCERNS ABOUT HIV AND TESTING

If you know that you are HIV positive, skip to question 44.

41. How worried are you about getting HIV or AIDS?
    0. Not at all
    1. Slightly
    2. Moderately
    3. Considerably
    4. Extremely

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42. How worried are you that you may have already been exposed to the HIV or AIDS virus?
    0. Not at all
    1. Slightly
    2. Moderately
    3. Considerably
    4. Extremely

43. How many times have you had a blood test for the AIDS virus (HIV)? (circle)
    0 1 2 3 4 5 6 7 8 9 10 or more times

44. When were you last tested for HIV? On the lines below, please write the month and year of your most recent test.

    Month ___ ___ /Year ___ ___ ___ ___

45. Were you ever told that you had the HIV, the AIDS virus?
    0. NO
    1. YES
    2. I never got the results

Thank You. Please let the staff person know that you have finished.

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FORM 18 - URINE TOXICOLOGY DURING SCREENING

(ONTRAK TESTCUP ONLY)

SCREEN FOR:

1. AMPHETAMINES ..... 1 Pos 2 Neg

2. COCAINE ..... 1 Pos 2 Neg

3. BARBITURATES ..... 1 Pos 2 Neg

4. OPIATES ..... 1 Pos 2 Neg

5. BENZODIAZEPINES ..... 1 Pos 2 Neg

NOTE: REFRIGERATE ONE-HALF URINE SAMPLE AND SHIP TO:

NWT, INC.
1141 EAST 3900 SOUTH
SALT LAKE CITY, UT 84124

FREEZE THE REMAINDER OF THE URINE SAMPLE AND RETAIN AT YOUR SITE UNTIL NOTIFIED BY CSPCC, PERRY POINT TO DISCARD.

FORM COMPLETED BY _____ Date _____

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Name Code	Center No.	Patient No.	Week	Date of Assessment
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FORM 19 - VITAL SIGNS

1. Weight (round to nearest lb.) ..... ___ ___ ___

2. Time Vital Signs taken (use 24 hr clock)..... ___ ___ : ___ ___

3. Temperature (oral) (Fº) ..... ___ ___ ___ . ___

4. Blood Pressure (sitting) (mm Hg) ..... ___ ___ ___ / ___ ___ ___

5. Pulse Rate (sitting) (beats/min) ..... ___ ___ ___

6. Respiratory Rate (sitting) (breaths/min) ..... ___ ___

7. Blood Pressure (standing 1 minute) (mm Hg)..... ___ ___ ___ / ___ ___ ___

8. Pulse Rate (standing 1 minute) (beats/min) ..... ___ ___ ___

9. Blood Pressure (standing 3 minutes) (mm Hg)..... ___ ___ ___ / ___ ___ ___

10. Pulse Rate (standing 3 minutes) (beats/min) ..... ___ ___ ___

FORM COMPLETED BY _____ Date _____

PHYSICIAN'S SIGNATURE _____ Date _____

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Selegiline Transdermal System

Name Code ☐☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐☐ Week ☐ Date of Assessment ☐☐-☐☐-☐☐☐☐ (Month-Day-Year)

FORM 20 - STUDY DRUG ACCOUNTABILITY

INSTRUCTIONS: Use the Comments section in the table below to explain all medication interruptions. Also record reasons for any discrepancy in the number of patches dispensed vs. the number of patches returned.

Day	Date (mo/day/yr)	Attended clinic?	No. patches dispensed	No. patches brought to clinic	Any medication discrepancy?	Patch applied:	Time patch applied (use 24 hr clock)	If patch not applied, medication interrupted by:	Comments
1	Enter Day: _____ Enter Date: _ _ _ _ _ _	1 ☐ Yes 2 ☐ No	_____	_____	1 ☐ Yes 2 ☐ No	1 ☐ By Patient 2 ☐ By Staff 3 ☐ Not applied	_ _ : _ _	1 ☐ Investigator 2 ☐ Patient/family 3 ☐ Other, specify in comments	
2	Enter Day: _____ Enter Date: _ _ _ _ _ _	1 ☐ Yes 2 ☐ No	_____	_____	1 ☐ Yes 2 ☐ No	1 ☐ By Patient 2 ☐ By Staff 3 ☐ Not applied	_ _ : _ _	1 ☐ Investigator 2 ☐ Patient/family 3 ☐ Other, specify in comments	
3	Enter Day: _____ Enter Date: _ _ _ _ _ _	1 ☐ Yes 2 ☐ No	_____	_____	1 ☐ Yes 2 ☐ No	1 ☐ By Patient 2 ☐ By Staff 3 ☐ Not applied	_ _ : _ _	1 ☐ Investigator 2 ☐ Patient/family 3 ☐ Other, specify in comments	
4	Enter Day: _____ Enter Date: _ _ _ _ _ _	1 ☐ Yes 2 ☐ No	_____	_____	1 ☐ Yes 2 ☐ No	1 ☐ By Patient 2 ☐ By Staff 3 ☐ Not applied	_ _ : _ _	1 ☐ Investigator 2 ☐ Patient/family 3 ☐ Other, specify in comments	
	Enter Day: _____	1 ☐ Yes	_____	_____	1 ☐ Yes	1 ☐ By Patient	_ _ : _ _	1 ☐ Investigator	

5	Enter Date: _ _ _ _ _ _	2 ☐ No			2 ☐ No	2 ☐ By Staff 3 ☐ Not applied		2 ☐ Patient/family 3 ☐ Other, specify in comments	
6	Enter Day: _____ Enter Date: _ _ _ _ _ _	1 ☐ Yes 2 ☐ No	_____	_____	1 ☐ Yes 2 ☐ No	1 ☐ By Patient 2 ☐ By Staff 3 ☐ Not applied	__ __ : __ __	1 ☐ Investigator 2 ☐ Patient/family 3 ☐ Other, specify in comments	
7	Enter Day: _____ Enter Date: _ _ _ _ _ _	1 ☐ Yes 2 ☐ No	_____	_____	1 ☐ Yes 2 ☐ No	1 ☐ By Patient 2 ☐ By Staff 3 ☐ Not applied	__ __ : __ __	1 ☐ Investigator 2 ☐ Patient/family 3 ☐ Other, specify in comments	

FORM COMPLETED BY _____ Date _____

SITE INVESTIGATOR'S SIGNATURE _____ Date _____

VA/NIDA STUDY 1019 Name Code ~~~~ Center No. ~~~ Patient No. ~~~~ Week ~~ Date of Assessment ~~-~~-

Selegiline Transdermal System ~~~~

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FORM 21 - ADVERSE EVENTS/CONCOMITANT MEDICATIONS

INSTRUCTIONS: Complete this form at study weeks 2 through 8, during the 1st visit of each study week, capturing all adverse events that occurred in the prior study week. (See Operations Manual/Data Management Handbook for instructions for coding of study week number).
Definition of adverse event: An adverse event is any untoward medical occurrence experienced by a patient after randomization. An adverse event includes an onset of disease, a set of related symptoms or signs, a single symptom or sign, or a clinically significant laboratory test change from baseline.

A. Has the patient experienced an adverse event since last adverse event assessment? 1 Yes**, give details below:** 9 2 No, go to Section D, page 2

(Interview patient regarding adverse events by asking a non-leading question such as "Have you felt differently in any way since your last clinic visit?")

I. Type of Report	**II.** Relatedness	**III.** Severity	**IV.** Action Taken	**V.** Outcome
1=Anticipated 2=Unanticipated 3=Intercurrent Illness 4=Withdrawal	1=Study Drug Related 2=Probably Study Drug Related 3=Possibly Study Drug Related 4=Unrelated to Study Drug	1=Mild 2=Moderate 3=Severe	1=None 2=Outpatient Treatment *3=Inpatient Treatment	1=Resolved; No Sequelae 2=Not Yet Resolved, But Improving 3=Not Yet Resolved, No Change 4=Not Yet Resolved, But Worsening *5=Resulted in Chronic Condition, Severe and/or Permanent Disability *6=Deceased 7=Unknown

Nature of Illness, Event, or Abnormal Lab Value	Date of Onset *(Mo Day Yr)*	I. Type of Report	II. Related-ness	III. Highest Level of Severity	IV. Action Taken	V. Outcome	If Resolved, Date of Resolution *(Mo Day Yr)* circle "c" if continuing	
1.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
2.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
3.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
4.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
5.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
6.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
7.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c

*Requires completion of Form 26 - Serious/Unexpected Adverse Event Form. NOTE: If adverse event is related to patch application, complete Form 22.
NOTE: If event is fatal, life-threatening, requires or prolongs hospitalization, is disabling or incapacitating, or a congenital abnormality, complete Form 26 (see Operations Manual, Section VII, for guidelines).

B. Is a Serious/Unexpected Adverse Event Form (Form 26) required? 1 Yes 2 No

C. Is Cutaneous Adverse Event Form (Form 22) required? 1 Yes 2 No

Comments (e.g., dose adjustment): _____

CSP 1019 - Form 21 (Page 2 of 2)

Name Code ~~~~ Center No. ~~~ Patient No. ~~~~ Week ~~ Date of Assessment ~~-~~-~~~~
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D. Has the patient taken any concomitant medications since last medication assessment? 1 Yes 2 No

If YES, enter all prescription and over-the-counter drugs taken therapeutically during the study including herbal preparations. Make a new entry when a dosage and/or frequency change occurs.

A GENERIC NAME OF MEDICATION	B If medication taken as a result of an adverse event, list number of event from previous page. If NOT, please list indication in next column.	C PURPOSE/ INDICATION	D ROUTE 1=Oral 2=Nasal 3=Intravenous 4=Inhalation 5=Topical transdermal 6=Intramuscular 7=Sublingual 8=Subcutaneous 9=Other	E DOSE	F UNITS 01=Capsule/Tablet 02=Drop 03=Milligram 04=Milliliter 05=Puff 06=Spray/squirt 07=Tablespoon 08=Teaspoon 09=Unknown 10=Other	G FREQUENCY 1=<1/day 2=1-4 /day 3=PRN 4=>4/day	H FROM Medication Start Date *(Mo/Day/Yr)* *circle "c" if continuing*		I TO Medication End Date (If ended, enter last date medication taken) *(Mo/Day/Yr)*
1.				_ _ _ _ . _ _ _	_ _	_____	_ _/ _ _/ _ _ _ _	c	_ _/_ _/_ _ _ _

2.				_ _ _ _ . _ _ _	_ _	_____	_ _ / _ _ / _ _ _ _	c	_ _ / _ _ / _ _ _ _
3.				_ _ _ _ . _ _ _	_ _	_____	_ _ / _ _ / _ _ _ _	c	_ _ / _ _ / _ _ _ _
4.				_ _ _ _ . _ _ _	_ _	_____	_ _ / _ _ / _ _ _ _	c	_ _ / _ _ / _ _ _ _

5.				_ _ _ _ . _ _ _	_ _	_____	_ _ / _ _ / _ _ _ _	c	_ _ / _ _ / _ _ _ _
6.				_ _ _ _ . _ _ _	_ _	_____	_ _ / _ _ / _ _ _ _	c	_ _ / _ _ / _ _ _ _
7.				_ _ _ _ . _ _ _	_ _	_____	_ _ / _ _ / _ _ _ _	c	_ _ / _ _ / _ _ _ _

8.				_ _ _ _ . _ _ _	_ _	_____	_ _ / _ _ / _ _ _ _	c	_ _ / _ _ / _ _ _ _
9.				_ _ _ _ . _ _ _	_ _	_____	_ _ / _ _ / _ _ _ _	c	_ _ / _ _ / _ _ _ _
10.				_ _ _ _ . _ _ _	_ _	_____	_ _ / _ _ / _ _ _ _	c	_ _ / _ _ / _ _ _ _

FORM COMPLETED BY _____ Date _____

PHYSICIAN'S SIGNATURE _____ Date _____

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Selegiline Transdermal System

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FORM 22 - CUTANEOUS ADVERSE EVENT REPORT FORM

(NOTE: Adverse event must also be reported on Form 21-Adverse Events/Concomitant Medications.)

1. Describe body site location of Cutaneous Adverse Event:_____

_____

2. Date of onset of reaction ..... __ __ - __ __ - __ __ __ __
(Mo) (Day) (Yr)

3. Outcome of reaction:

A. Resolved ..... __ __ - __ __ - __ __ __ __
(Mo) (Day) (Yr)

OR

B. Still present* ..... __ __ - __ __ - __ __ __ __
(Mo) (Day) (Yr)

*If reaction is still present at termination, provide details: _____

_____

_____

4. Was treatment required for this event? ..... 1___Yes 2___ No

A. If Yes, specify: _____

5. Indicate the highest level of severity of this event that was observed by staff .....1___Mild 2___Moderate 3___Severe 4___None

6. Was the event serious? (a serious adverse event includes any experience that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly) ..... 1___ Yes** 2___ No

*****If the event was SERIOUS, the event must be reported within 24 hours and recorded on Form 26. (See guidelines for reporting SAE's in the Operations Manual, Section VII.)***

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				Month Day Year

7. What is the likelihood of relationship to the patch?

1___ None 2___ Remote 3___ Possible 4___ Probable 5___ Highly probable

8. Has this reaction occurred with patches previously applied at the body site location described in Q.1? ..... 1___ Yes 2___ No 3___ NA

A. If Yes, how frequently does it occur? _____

9. Choose **<u>one</u>** dermal response category below which most accurately describes this cutaneous adverse event at its **<u>highest level of severity observed by staff</u>** ..... _____

1 = No evidence of irritation
2 = Minimal erythema, barely perceptible
3 = Definite erythema, readily visible, minimal edema or minimal papular response
4 = Erythema and papules
5 = Definite edema
6 = Erythema, edema, and papules
7 = Vesicular eruption
8 = Strong reaction spreading beyond test site

10. Describe the course of the cutaneous adverse event: _____

_____

_____

_____

_____

_____

FORM COMPLETED BY _ Date _

PHYSICIAN'S SIGNATURE _ Date _

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Name Code	Center No.	Patient No.	Week	Date of Assessment
~ ~ ~ ~	~ ~ ~	~ ~ ~ ~ ~	~ ~	~ ~ – ~ ~ – ~ ~ ~ ~
				Month Day Year

FORM 23 - URINE BE COLLECTION

First Sample of Study Week

1. Date of sample ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

Second Sample of Study Week

2. Date of sample ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

Third Sample of Study Week

3. Date of sample ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

_____

___

FORM COMPLETED BY _____ Date _____

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VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code ~~~~ Center No. ~~~ Patient No. ~~~~ Week ~ Date of Assessment ~~ – ~~ – ~~~~
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FORM 24 - BEHAVIORAL TREATMENT

1. Did patient attend the manual guided weekly treatment session with the study therapist? ..... 1 Yes (go to Q.1A) 2 No (go to Q.2)

If Yes, enter date and length of session:

A. Date and length ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___ ___ ___ ___ (min)

B. Date and length ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___ ___ ___ ___ (min)

2. Did patient have an emergency crisis management session with the study therapist? ..... 1 Yes (go to Q.2A) 2 No (go to Q.3)

If Yes, enter date and length of each session:

A. Date and length ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___ ___ ___ ___ (min)

B. Date and length ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___ ___ ___ ___ (min)

3. Did patient receive psychosocial treatment from someone other than the study therapist?..... 1 Yes (go to Q.3A) 2 No (stop)

If Yes, enter source of therapy, date, and length of session:

A. 1___AA 2___NA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

B. 1___AA 2___NA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

C. 1___AA 2___NA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

D. 1___AA 2___NA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

E. 1___AA 2___NA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

F. 1___AA 2___NA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

G. 1___AA 2___NA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

FORM COMPLETED BY _____ Date _____

VA/NIDA STUDY 1019
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Name Code ~ ~ ~ ~ Center No. ~ ~ ~ Patient No. ~ ~ ~ ~ Week ~ Date of Assessment ~ ~ - ~ ~ - ~ ~ ~ ~
Month Day Year

FORM 25 - BRIEF SUBSTANCE CRAVING SCALE

Please answer the following questions with regard to craving for Cocaine.

1. The INTENSITY of my craving, that is, how much I desired cocaine in the past 24 hours was:

   0 ~ None at all 1 ~ Slight 2 ~ Moderate 3 ~ Considerable 4 ~ Extreme

2. The FREQUENCY of my craving, that is, how often I desired cocaine in the past 24 hours was:

   0 ~ Never 1 ~ Almost never 2 ~ Several times 3 ~ Regularly 4 ~ Almost constantly

3. The LENGTH of time I spent in craving for cocaine during the past 24 hours was:

   0 ~ None at all 1 ~ Very short 2 ~ Short 3 ~ Somewhat long 4 ~ Very long

4. Write in the NUMBER of times you think you had craving for cocaine during the past 24 hours:

   ~ ~

5. Write in the total TIME spent craving cocaine during the past 24 hours:

   ~ ~ Hours ~ ~ Minutes

6. WORST day: During the past week my most intense craving occurred on the following day:

   1 ~ Sunday 2 ~ Monday 3 ~ Tuesday 4 ~ Wednesday

   5 ~ Thursday 6 ~ Friday 7 ~ Saturday 8 ~ All days the same (go to Q.8)

7. The date for that day was: ~ ~ - ~ ~ - ~ ~ ~ ~

8. The INTENSITY of my craving, that is, how much I desired cocaine on that worst day was:

   0 ~ None at all 1 ~ Slight 2 ~ Moderate 3 ~ Considerable 4 ~ Extreme

Name Code ~~~~ Center No. ~~~ Patient No. ~~~~ Week ~ Date of Assessment ~~-~~-~~~~
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9. A 2nd craved drug during the past 24 hours was: (mark ONLY ONE of the following)
(If no 2nd craved drug, mark 0=None and leave questions 10-16 blank.)

0 ~ None 1 ~ Downers or Sedatives 2 ~ Benzos (Valium, Xanax, etc.)

3 ~ Nicotine 4 ~ Alcohol (Barbiturates, etc.) 5 ~ Heroin or other Opiates

6 ~ Marijuana 7 ~ Others (Morphine, etc.)

10. The INTENSITY of my craving, that is, how much I desired this second drug in the past 24 hours was:

0 ~ None at all 1 ~ Slight 2 ~ Moderate 3 ~ Considerable 4 ~ Extreme

11. The FREQUENCY of my craving, that is, how often I desired this second drug in the past 24 hours was:

0 ~ Never 1 ~ Almost never 2 ~ Several times 3 ~ Regularly 4 ~ Almost constantly

12. The LENGTH of time I spent in craving for this second drug during the past 24 hours was:

0 ~ None at all 1 ~ Very short 2 ~ Short 3 ~ Somewhat long 4 ~ Very long

13. A 3rd craved drug during the past 24 hours was: (mark ONLY ONE of the following)
(If no 3rd craved drug, mark 0=None and leave questions 14-16 blank.)

0 ~ None 1 ~ Downers or Sedatives 2 ~ Benzos (Valium, Xanax, etc.)

3 ~ Nicotine 4 ~ Alcohol (Barbiturates, etc.) 5 ~ Heroin or other Opiates

6 ~ Marijuana 7 ~ Others (Morphine, etc.)

14. The INTENSITY of my craving, that is, how much I desired this third drug in the past 24 hours was:

0 ~ None at all 1 ~ Slight 2 ~ Moderate 3 ~ Considerable 4 ~ Extreme

15. The FREQUENCY of my craving, that is, how often I desired this third drug in the past 24 hours was:

0 ~ Never 1 ~ Almost never 2 ~ Several times 3 ~ Regularly 4 ~ Almost constantly

16. The LENGTH of time I spent in craving for this third drug during the past 24 hours was:

0 ~ None at all 1 ~ Very short 2 ~ Short 3 ~ Somewhat long 4 ~ Very long

FOR STAFF ONLY:

FORM REVIEWED BY _____ Date

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Selegiline Transdermal System

Name Code	Center No.	Patient No.	Week	Date of Assessment
~ ~ ~ ~	~ ~ ~	~ ~ ~ ~	~	~ ~ – ~ ~ – ~ ~ ~ ~
				Month Day Year

FORM 26 - SERIOUS/UNEXPECTED ADVERSE EVENT FORM

A. ADVERSE EVENT:

1. Adverse Event: _____

2. Date of Onset.....Mo __ __ Day __ __ Yr __ __ __ __

3. Age of Patient.....__ __

4. Sex of Patient (**1**=Male, **2**=Female).....____

5. Patient's Height (inches)..... __ __ . __

6. Patient's Weight (pounds)..... __ __ __

7. Provide Narrative Description of Event _____
_____
_____
_____
_____

a. Greatest Severity (**1**=Mild, **2**=Moderate, **3**=Severe) ..... ____

b. Study Drug Related?..... ____
1=Definitely Study Related, **2**=Probably Study Related,
3=Possibly Study Related, **4**=Unrelated to Study

c. Action Taken? (**1**=None, **2**=Outpatient Treatment, **3**=Inpatient Treatment) ..... ____

d. Was dose interrupted? (**1** = Yes, **2** = No) ..... ____

1. If yes, specify total number of days drug was not given ..... __ __

e. Did event abate after study drug stopped? (**1** = Yes, **2** = No, **3** = NA) ..... ____

f. Did event reappear after drug was reintroduced? (**1** = Yes, **2** = No, **3** = NA) ..... ____

g. Outcome to date?..... ____

1=Resolved; no sequelae	**5**=Resulted in chronic condition, severe and/or permanent disability
2=Not yet resolved, but improving	
3=Not yet resolved, no change	**6**=Deceased
4=Not yet resolved, worsening	**7**=Unknown

h. Terminated? (**1** = Yes, **2** = No)..... ____
(If terminated, complete Termination Form 27.)

Name Code	Center No.	Patient No.	Week	Date of Assessment
~ ~ ~ ~	~ ~ ~	~ ~ ~ ~	~	~ ~ – ~ ~ – ~ ~ ~ ~
				Month Day Year

8. If patient died, date of death ..... Mo __ __ Day __ __ Yr __ __ __ __

A. Cause of Death: _____

9. Relevant Tests/Laboratory Data: …

B. SUSPECT DRUG(S) INFORMATION:

10. Suspect Drug(s): ..... ____
1=Study drug, **2**=Nonstudy drug(s), **3**=Combination (study drug & nonstudy drug), **4**=NA (not drug)

11. If Non-study drug(s)

a. Trade/generic name of drug(s):

1) _____ 3) _____

2) _____ 4) _____

b. Dose, regimen, routes of administration:

1) _____ 3) _____

2) _____ 4) _____

c. Dates of Administration:

1) FROM: __ __ / __ __ / __ __ __ __ TO: __ __ / __ __ / __ __ __ __
Mo Day Year Mo Day Year

2) FROM: __ __ / __ __ / __ __ __ __ TO: __ __ / __ __ / __ __ __ __
Mo Day Year Mo Day Year

3) FROM: __ __ / __ __ / __ __ __ __ TO: __ __ / __ __ / __ __ __ __
Mo Day Year Mo Day Year

4) FROM: __ __ / __ __ / __ __ __ __ TO: __ __ / __ __ / __ __ __ __
Mo Day Year Mo Day Year

d. Indication(s) for Use:

1) _____ 3) _____

2) _____ 4) _____

FORM COMPLETED BY Date

PHYSICIAN'S SIGNATURE Date

SITE INVESTIGATOR'S SIGNATURE Date

VA/NIDA STUDY 1019
Selegiline Transdermal System

Name Code	Center No.	Patient No.	Week	Date of Assessment
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				Month Day Year

FORM 27 - STUDY COMPLETION/TERMINATION

1. Date of last clinic visit ..... Mo __ __ Day __ __ Yr __ __ __ __

2. Date study patch last dispensed to patient ..... Mo__ __ Day __ __ Yr __ __ __ __

3. Was patient dispensed study patch during last week of study? ..... 1___ Yes 2___ No

4. Did patient complete study participation (i.e., provide at least one urine sample during week 8 of treatment)? ..... 1___ Yes 2___ No

If YES, sign form below. If NO, go to Q. 5.

5. Code PRIMARY reason for early termination ..... ___ ___

01 = Toxicity or side effects related to study medication (complete Adverse Event Form 21)
02 = Medical reason unrelated to study medication which prevents study participation,
specify _____
03 = Termination by clinic physician because of intercurrent illness or medical complication which prevents safe administration of study medication,
specify _____
04 = Administrative discharge, specify _____
05 = Failed to return to clinic
06 = Patient's request, specify _____
07 = Moved from area
08 = Incarceration
09 = Pregnancy
10 = Death (complete Serious Adverse Event Form 26)
11 = Other, specify _____

FORM COMPLETED BY _ Date _

SITE INVESTIGATOR'S SIGNATURE _ Date _

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Name Code	Center No.	Patient No.	Week	Date of Assessment
~~	~~~	~~~~	~~	~~ – ~~ – ~~~~
				Month Day Year

FORM 28 - FOLLOW-UP

COMPLETE THIS FORM <u>FOR ALL PATIENTS</u> APPROXIMATELY 30 DAYS AFTER PATIENT TERMINATES.

1 = YES
2 = NO

1. Has contact been made with the patient? ..... _____
(If YES, complete a-e, and Q.5. If NO, go to Question 2.)

a. If **YES**, date of contact ..... Mo __ __ Day __ __ Yr __ __ __ __

b. Does the patient report currently using cocaine illicitly? _____

c. Does the patient report currently using other drugs illicitly? _____

d. Does the patient report currently receiving treatment for drug or alcohol abuse/dependence? _____

e. Does the patient report that he/she would take the study medication again if it were generally available for cocaine-dependence treatment? _____

2. If contact has not been made with the patient, code reason ..... _____
1 = Unable to contact
2 = Other reason, specify _____

3. If unable to reach patient, has contact been made with someone who can verify his/her status? _____

a. If **YES**, date of contact ..... Mo __ __ Day __ __ Yr __ __ __ __
(If YES, go to **Question 4**)

b. If **NO**, explain _____

4. Has the patient died? _____
If **YES**:

a. Date of Death ..... Mo __ __ Day __ __ Yr __ __ __ __

b. Cause of Death _____

c. Information verified by site staff (e.g., coroner's office, death certificate) _____

5. Additional Comments: _

-

FORM COMPLETED BY _ Date _____

SITE INVESTIGATOR'S SIGNATURE _____ Date _____