POLICY AND PROCEDURES

OFFICE OF COMMUNICATIONS

FDA Pharmacy Student Experiential Program

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PURPOSE

This MAPP outlines CDER policies, procedures, and practices for CDER participating office and division directors, administrative or management officers, preceptors, and pharmacy students in the FDA Pharmacy Student Experiential Program (FDA PSEP).

BACKGROUND

The FDA PSEP offers unpaid training opportunities to eligible pharmacy students. This experience is part of the pharmacy students' academic curriculum to develop their professional skills.

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The FDA PSEP provides an opportunity to learn about the FDA's multidisciplinary processes for addressing public health issues involving drugs, biologics, and medical devices.

POLICY

Eligibility

- Preceptors must be FDA employees and have supervisory concurrence.
- Pharmacy students must be U.S. citizens.
 - o Be enrolled in an accredited pharmacy school.
 - o Have completed his or her pharmacy school's requirements to start experiential programs.
 - o Apply to and be accepted into the FDA PSEP.

Policies

- Pharmacy students:
 - o Agree to not divulge non–public information.
 - o Must be supervised by an FDA employee, serving as preceptor.
 - o Do not receive Federal appointments. Their service is not reported to the Central Personnel Data File (CPDF).
- The Office of Human Resources (OHR) cannot use an Official Personnel Folder for documenting pharmacy student service. However, it is recommended that the preceptor retain a record of each pharmacy student's rotation documentation (including Student Volunteer Service Agreement, Commitment to Protect Confidential and Privileged Information, and evaluation) for three years.
- Pharmacy students are subject to FDA security processes. Pharmacy students may be subject to the investigative requirements of Executive Order 10450, "Security Requirements for Government Employment."

Confidential Information

• In the course of its work, FDA handles and utilizes a large amount of confidential and privileged information. The FDA has a legal obligation to make every effort to safeguard such confidential and privileged information from intentional or inadvertent release.

Compensation

- FDA PSEP is an unpaid service program. No compensation is provided.
- Preceptors will not accept honoraria.

Program Time Frame

• Pharmacy students are on short-term assignments, typically six 40-hour weeks.

FDA PSEP Services and Benefits

- Pharmacy students are considered employees of the Federal Government for the purposes of the benefits provided by U.S.C. 8101 for work-related injuries or diseases. In case of injury sustained by a pharmacy student while in the performance of duty, the procedures applicable to federal government employees should be followed.
- Like Federal employees, pharmacy students are covered by the tort claims provisions of Title 28, U.S. Code.
- Pharmacy students may be provided protective clothing and equipment under 5 U.S.C. 7903, in order to prevent work-related injuries.
- Pharmacy students will receive emergency outpatient treatment for injuries sustained
 while performing assigned FDA PSEP duties. Pharmacy students may also be
 provided temporary care and treatment in Agency facilities under the same
 circumstances and to the same extent such care and treatment are available to paid
 employees as covered by 213-1 Student Educational Employment Program and
 Student Volunteer Employment Program Handbook.

Termination of Employment

• The FDA PSEP arrangements may be terminated at any time by the school, preceptor, or the pharmacy student. When a pharmacy student is terminated during or at the end of the scheduled rotation, the Administrative Officer (AO) or Management Officer (MO) is notified. The pharmacy student completes the eDepart procedure and returns the FDA badge to the AO or MO. If the AO or MO is not available, the pharmacy student returns the badge to the preceptor.

RESPONSIBILITIES

Office or Division Director, or designee:

- Approves requests for participation in the FDA PSEP.
- Ensures the pharmacy student completes the eDepart procedure, as appropriate.

FDA PSEP Program Director or designee:

- Develops and manages the annual selection process.
- Ensures day-to-day operations.
- Responds to inquiries, as appropriate.

Preceptor:

• Must gain supervisor concurrence prior to participating in PSEP.

- Participates in the annual selection process to review the pharmacy student applications to identify the best candidate(s) for the office or division.
- Ensures the pharmacy student is available for proposed rotation dates.
- Sends Acceptance email and <u>FDA Pharmacy Student Experiential Program Student Volunteer Service Agreement</u> within 2 weeks of selecting student. (See Sample FDA PSEP Acceptance letter, Attachment 1 and <u>FDA Pharmacy Student Experiential Program Student Volunteer Service Agreement</u> (Attachment 3.)
- Sends the following to the pharmacy student at least 10 weeks before the scheduled start date:
 - 1. Specific office or division FDA PSEP Learning Objectives. (Attachment 2.)
 - 2. Pharmacy Student Experiential Program eArrive Questionnaire (Attachment 4.)
 - 3. This MAPP.
- Completes and signs the affiliation agreement for each school of pharmacy, as needed.
- Ensures the <u>FDA Pharmacy Student Experiential Program Student Volunteer Service</u> <u>Agreement</u> is signed by the preceptor, the division director or designee, the pharmacy student's school, the pharmacy student, and OHR.
- Provides a copy of the signed <u>FDA Pharmacy Student Experiential Program Student Volunteer Service Agreement</u> to the pharmacy student, the pharmacy student's school, and maintains a copy in the division or office.
- Confirms completed paperwork is received by FDA security. To identify the CDER security contact, see the "Personnel Security Branch Points of Contact" document in the FDA Pharmacy Student Experiential Program: Preceptor Resource Library intranet page.
- Ensures the pharmacy student completes all on-boarding FDA-required training as indicated in the email from FDA security.
- Sends an email to the pharmacy student with instructions for reporting on the first day of work, at least one week before start date. The email includes the following:
 - 1. Building address.
 - 2. Parking information.
 - 3. Directions regarding front entrance security and required escort.
 - 4. Duty hours.
 - 5. A reminder to bring two forms of identification, at least one with a photograph, to be used when completing paperwork with the AO or MO.
 - 6. Suggestion of business casual dress code.
- Ensures the pharmacy student is scheduled, and escorts are arranged, for the following two appointments for the pharmacy student's first work day:

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First: Appointment with the AO or MO, to complete the HHS-745, "HHS ID Badge Request."

Second: White Oak badging office.

- On the first day of the rotation, discusses the definition of confidential and privileged information with the pharmacy student. Instructs the student on his or her responsibility to protect this information. Acts as a witness when the pharmacy student signs the <u>Commitment to Protect Confidential and Privileged Information</u>. (Attachment 5.)
- Tracks the pharmacy student's hours and days of service.
- Teaches, guides, and supervises the pharmacy student.
- Provides an evaluation of the pharmacy student's FDA PSEP performance as required by the pharmacy school.
- Collects the following at the end of the rotation for the AO or MO:
 - 1. FDA badge.
 - 2. Government equipment.
- Ensures the pharmacy student completes the eDepart procedure as indicated in the eDepart email.
- Ensures the FDA PSEP evaluations are maintained for three years in the division where the pharmacy student completed the program.

Pharmacy Student:

Application process-

- Applies to the FDA PSEP through his or her college or university.
- Ensures his or her pharmacy school is in agreement with the *FDA Pharmacy Student Experiential Volunteer Service Agreement*.

If accepted to the program-

Completes and returns to the preceptor the following at least nine weeks before FDA PSEP program start date the:

- o <u>FDA Pharmacy Student Experiential Program Student Volunteer Service</u> <u>Agreement.</u>
- o Pharmacy Student Experiential Program eArrive Questionnaire.
- Completes and returns the e-QIP Initiation Form to FDA Security within the
 timeframe given in the email from FDA Security. (It is required for security to
 initiate the pharmacy student's background clearance process). After the e-QIP
 Initiation Form is completed and submitted to FDA Security, completes and
 submits the following forms as directed in FDA Security email.

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- o Questionnaire for Non-Sensitive Positions (SF-85P).
- o Declaration for Federal Employment Form (OF-306).
- o Form FD-258, FBI fingerprint form (if not living within one hundred miles of White Oak).

Pharmacy students living within one hundred miles of White Oak, Maryland, will schedule an appointment at the White Oak badging office and turn in his or her HHS-745 form and perform fingerprinting in advance of the rotation start date, as directed in the email from FDA Security. On the first day of the rotation, the pharmacy student may pick up the badge, unescorted, at the White Oak badging office.

- Completes the Annual Computer Security Awareness training and emails the certificate of completion to the preceptor.
- Discusses any expected absence with the preceptor before arrival on rotation site.

During the FDA PSEP Program-

- On the first day:
 - o Completes HHS-745 "HHS ID Badge Request" form in the presence of an AO or MO (if not already completed).
 - o Obtains badge from the White Oak badging office.
- Discusses responsibility to protect confidential and privileged information with the preceptor. Signs Commitment to Protect Confidential and Privileged *Information* in the presence of the preceptor.
- If the pharmacy student intends to publish or otherwise disclose the work performed while at CDER, the pharmacy student must obtain advance clearance from CDER in accordance with CDER MAPP 4510.2, CDER Clearance of FDA-Related Articles, Speeches, and Other Publications and his or her preceptor.
- Completes all required training as directed by his or her preceptor.

Upon completion of the FDA PSEP Program-

- Turns in the FDA badge. If the AO or MO is not available the preceptor will hold the badge until the AO or MO is available to accept the badge.
- Turns in any government equipment.
- Completes the eDepart procedure on the last day of rotation.
- Continues to protect any confidential and privileged information.

Administrative Officer or Management Officer:

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- Ensures the preceptor sends the pharmacy student the *Pharmacy Student Experiential Program eArrive Questionnaire* at least ten weeks before the pharmacy student's start date.
- Enters the pharmacy student into eArrive no more than nine weeks prior to the FDA PSEP start date.
- Verifies receipt of all the pharmacy student documents in eArrive.
- Enters student's information into the Identity System immediately after the student's information has been placed in eArrive.
- Completes and sends the Computer Account Request Form to the appropriate group.
- Notifies the preceptor if there are any outstanding issues.
- Reminds the preceptor to schedule an appointment for the pharmacy student to meet with the AO or MO to complete the HHS-745, "HHS ID Badge Request," (single-sided signed hard copy) form on the first day of the pharmacy student's experience, if the student is not living within one hundred miles of White Oak. This form must be signed with the AO or MO present.
- Initiates eDepart procedures.
- Collects the following at the end of the rotation:
 - 1. FDA badge.
 - 2. Government equipment.
 - 3. Ensure the pharmacy student completes the eDepart process as indicated in the eDepart email.

PROCEDURES

I. Application Process

- 1. Pharmacy student applies to the FDA PSEP in the year preceding the last year of pharmacy school. The deadline is posted on the FDA PSEP website.
- 2. Pharmacy student ensures the following documents are submitted in accordance to the instructions on the FDA PSEP Website:
 - o Resume or curriculum vitae.
 - One-page statement on how a rotation at FDA would facilitate achievement of career goals.
 - Three potential time slots for rotation, keeping in mind that flexible rotation slots will expand placement opportunities.
 - o Three preferred rotation sites.

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- 3. If accepted to the program, pharmacy student agrees to specific rotation dates. The pharmacy student informs his or her preceptor of any expected absences during the rotation as early as possible.
- 4. Pharmacy student completes and returns the following documents at least nine weeks before the FDA PSEP program start date:
 - FDA Pharmacy Student Experiential Program Student Volunteer Service Agreement
 - o Pharmacy Student Experiential Program e-Arrive Questionnaire
- 5. Pharmacy student completes and returns the e-QIP Initiation Form to FDA Security.
- 6. After the e-QIP Initiation Form is submitted, pharmacy student completes and returns the following to FDA Security per instructions provided in the email from FDA security:
 - o Questionnaire for Non-Sensitive Positions (SF-85P).
 - o Declaration for Federal Employment Form 306.
 - o Form FD-258, FBI fingerprint form.
- 7. Pharmacy student completes Annual Computer Security Awareness training. (Email the certificate of completion to the preceptor.)

II. Student Selection

- 1. The preceptor selects the pharmacy student(s).
- 2. The preceptor sends an acceptance email to each pharmacy student within two weeks of selection. See Sample Acceptance Letter, Attachment 1.
- 3. The preceptor sends each student the <u>FDA Pharmacy Student Experiential</u> <u>Program Volunteer Service Agreement</u> and the Learning Objectives for the office or division.

III. Onboarding

- 1. The pharmacy student completes and returns the approved <u>FDA Pharmacy</u> <u>Student Experiential Program Student Volunteer Agreement</u> to the preceptor.
- 2. Upon receipt of the completed <u>FDA Pharmacy Student Experiential Program Student Volunteer Agreement</u>, the preceptor submits to the office or division director for signature.
- 3. The preceptor forwards the appropriate documents to the pharmacy student at least 10 weeks before the start of the FDA PSEP rotation, including:
 - o Specific office or division FDA PSEP Learning Objectives. (Attachment 2.).

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- Pharmacy Student Experiential Program eArrive Questionnaire (eArrive Data Form).
- o This MAPP.
- 4. The pharmacy student returns the following completed documents in accordance with instructions in the FDA Security email:
 - o e-QIP Initiation Form
 - o Declaration for Federal Employment Form 306
 - o Form FD-258, FBI fingerprint form.
 - o Questionnaire for Non-Sensitive Positions (SF-85P)
- 5. The AO or the MO verifies student's documents are complete, and the Declaration of Federal Employment form (OF-306) and the Form FD-258 are submitted to FDA Security Office.
- 6. The AO or the MO enters the student's personal identifiable information into the eArrive system no more than nine weeks prior to the student's start date. Once the AO or MO enters the student's record into eArrive, the Security office will send an email with the e-QIP Initiation Form and additional instructions.
- 7. The AO or the MO enters the student's information into the Identity System immediately after the student's information has been placed in eArrive.
- 8. Upon email receipt of e-QIP Initiation Form, the pharmacy student completes the e-QIP Application (SF-85P) and submits signature pages to the FDA Security Office.
- 9. The pharmacy student completes the Annual Computer Security Awareness training at least one week prior to start date.
- 10. The preceptor sends an email to the pharmacy student with instructions for reporting on the first day of work, one week before start date. The email includes the following:
 - 1. Building address
 - 2. Parking information
 - 3. Directions regarding front entrance security and required escort
 - 4. Suggestion of business casual dress code
 - 5. Duty hours
 - 6. A reminder to bring two forms of identification, at least one with a photograph, to be used when completing paperwork
- 11. The preceptor ensures arrangements for the pharmacy student to meet with the AO or MO, with the White Oak badging office, on the first day of the FDA PSEP experience, if not already completed prior to the first day of rotation.
- 12. On the first day of the rotation, the preceptor discusses the definition of confidential and privileged information with pharmacy student and instructs the

student on his or her responsibility to protect this information. The preceptor acts as a witness when the pharmacy student signs the Commitment to Protect Confidential and Privileged Information.

IV. The FDA PSEP Experience:

The preceptor:

- 1. Works with the pharmacy student throughout the FDA PSEP experience to ensure the pharmacy student has a productive experience.
- 2. Serves as supervisor to the pharmacy student.
- 3. Tracks the pharmacy student's hours and days of service.
- 4. Completes any documentation required by the pharmacy school related to the FDA PSEP experience.

FDA PSEP Exit Activities:

The preceptor:

- 1. Prepares the pharmacy school's evaluation of the pharmacy student's performance, as required by the pharmacy school.
- 2. Keeps a copy of the pharmacy student's performance evaluation in the division records for three years.
- 3. Collects and returns the pharmacy student's badge if the AO or MO is not available. The preceptor will hold the badge until the AO or MO is available to accept the badge.
- 4. Ensures the completion of the eDepart procedure prior to close of business on the last day of FDA PSEP rotation.

The pharmacy student:

- 1. Turns in the FDA badge and equipment to the AO or MO by close of business on the last day of the FDA PSEP rotation. If the AO or MO is not available the preceptor will hold the badge until the AO or MO is available to accept the badge.
- 2. Completes the eDepart procedure prior to close of business on the last day of FDA PSEP rotation.

The Administrative or Management Officer:

- 1. Initiates the eDepart procedure.
- 2. Collects FDA badge and submits to FDA Security.
- 3. Collects FDA equipment.

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REFERENCES

- 1. Executive Order 10450, as amended, 1978. Security Requirements for Government Employment.
- 2. U.S.C. 2009, Salary of Government officials and employees payable only by United States.
- 3. 5 U.S.C. 8101, The Federal Employees' Compensation Act (FECA).
- 4. 5 U.S.C. 7903, Protective Clothing and Equipment.
- 5. 5 U.S.C. Subpart 3111, Acceptance of Volunteer Service.
- 6. Title 28, U.S.C. Judiciary and Judicial Procedure.
- 7. HHS, 2008, Instruction 213-1: Student Educational Employment Program and student Volunteer Program Handbook pp 18-20.
- 8. HHS, 2014, Human Resources Manual, Instruction213-1 Student Educational Program and Student Volunteer Employment Program Handbook.
- 9. FDA, 2013, CDER for Drug Evaluation and Research, MAPP 4510.2. Clearance of Speeches, Articles, and Other Communication Materials.
- 10. FDA, 2013, CDER for Drug Evaluation and Research, MAPP 4642.3. Student Volunteer Employment Program (SVEP).
- 11. 21 CFR, Part 20, Public Information.
- 12. 213-1 Student Educational Employment Program and Student Volunteer Employment Program Handbook

DEFINITIONS

FDA Pharmacy Student Experiential Program (FDA PSEP): A government program designed to provide a pharmacy student, as part of his or her school experiential rotation, the opportunity to become acquainted with the workings of a Federal agency, government regulations and rule-making, and government administration. The FDA PSEP provides an opportunity to learn about the FDA's multidisciplinary processes for addressing public health issues involving drugs, biologics, and medical devices. FDA PSEP pharmacy students can provide benefits to the CDER with services such as conducting literature searches, or preparing summaries of findings upon completion of special projects. The FDA PSEP participation is to be uncompensated and will not be used to displace any employee or to staff a position that is a normal part of the CDER's work force.

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Onboarding: the process in which an individual is welcomed and acclimated before starting the pharmacy student experiential program rotation at FDA.

Preceptor: A FDA employee who is responsible for the teaching, guiding, and supervising of a pharmacy student at FDA. This FDA employee is in a specialized field that requires knowledge characteristically acquired through education or training equivalent to a bachelor's or higher degree, with a major in or pertinent to the specialized field, as distinguished from general education. The employee serving as preceptor should be in a position that relates to pharmacy. However, depending upon the criteria of participating schools, other professionals may serve as preceptors.

Pharmacy student: An individual who is enrolled in the study of pharmacy at a college, university, or other accredited educational institution.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective	Revision	Revisions
Date	Number	
12/21/15	N/A	Initial
8/28/19	1	Limit eligibility to U.S. citizens

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ATTACHMENT 1: Sample FDA PSEP Acceptance Letter

Food and Drug Administration [Preceptor's business address] [Preceptor's room number] Silver Spring, MD [Zip code]

[Month/Date/Year]

[Email student, and cc College or University Experiential coordinator] [Note to preceptor: Attach Learning Objectives, MAPP 4410.1, and attachments 3 and 4 of MAPP 4410.1.]

Dear [insert name] and [insert experiential coordinator's name]:

Congratulations on your selection for a rotation in the [insert division's name] at the Food and Drug Administration! You indicated that your first choice for dates is [month/date/year], and your second choice is [month/date/year]. Both these periods are currently available. If you are interested in this rotation, please let me know which you prefer. Please read this letter and follow the instructions.

You should receive paperwork with submission instructions at least ten weeks prior to your start date. (Please check your junk or spam email folder and contact me if any paperwork is not received.) Due to the need to conduct a background investigation prior to participating in the FDA Pharmacy Student Experiential Program, it is necessary to adhere to strict timeframes for submission of required forms and information, to ensure that your rotation preparation runs smoothly.

Experiential coordinator, please make sure your office and the student complete the Pharmacy Student Experiential Program Student Volunteer Service Agreement (Attachment 3) of the CDER MAPP 4410.1, enclosed.

Please send the signed Pharmacy Student Experiential Program eArrive Questionnaire (Attachment 4 of CDER MAPP 4410.2) to my attention at [preceptor's email address] or:

[Preceptor's business address] [Preceptor's room number] Silver Spring, MD [Zip code]

It is necessary to plan with as much advanced notice as possible to make sure we have adequate space.

As a critically important reminder, the FDA does not provide assistance with housing, or a per diem to visiting students. You may find information about housing on our Web site at: http://www.fda.gov/pharmstudentprogram

Please also bring two forms of picture identification (driver's license, passport, or student ID) with you.

Limited parking is available on site at no charge, provided that the background investigation paperwork has been completed. In general, the work day is from approximately 8:00 AM to 4:30 PM M-F and, of course, you will be granted all Federal holidays.

I look forward to meeting you!

Best regards,
[Signature block]

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Enclosures: FDA PSEP Agreement, MAPP 4410, 1"FDA Pharmacy Student Experiential Program", HHS-745 ID Badge Request Form, eArrive Questionnaire, office or division learning objectives,

ATTACHMENT 2: Sample FDA PSEP Learning Objectives

Pharmacy Student Rotation in the Food and Drug Administration's CDER for Drug Evaluation and Research (CDER), Division of Drug Information

Goals: The purpose of this rotation is to familiarize the student with the role of the Food and Drug Administration (FDA) in the drug development, review, and post-marketing phases, as well as offer experience in providing drug information to consumers, health care professionals, and industry.

- I. Learning Objectives: Upon completion of this rotation the student will be able to:
 - A. Describe the development of a new drug from laboratory to commercial distribution of the product and the FDA's role in that process.
 - B. Distinguish between the three phases of clinical trials in the drug development process.
 - C. Discuss ways the FDA makes new drugs available to patients prior to approval.
 - D. Outline the post-marketing surveillance mechanisms the FDA uses to assure drugs remain safe and effective for the American people.
 - E. Utilize drug information and FDA resources such as Medline, Micromedex, and the Federal Register, and become familiar with what type of information is posted on the FDA's Web page and CDER's Internet.
 - F. Answer questions /become familiar with the laws, regulations, and guidance documents governing drugs.
 - G. Respond to inquiries regarding FDA approved products.
- II. Student Requirements: The student will be exposed to a variety of questions regarding all aspects of pharmaceuticals and the pharmaceutical industry. The program will focus on familiarizing the student with the type of information collected and what is releasable from the FDA. To meet these objectives the student will be expected to:
 - A. Meet with preceptor at the beginning of the rotation to review the student lecture series and meeting schedules.
 - B. Respond to drug information requests from consumers regarding general drug information, adverse effects, and potential drug interactions.
 - C. Return all phone calls the same day.
 - D. Be familiar with current drug news in the media.
 - E. Give a presentation or conduct a project assigned by preceptor.
 - F. Participate and present an article in Journal Club as determined by preceptor.
 - G. Fulfill required hours.
 - H. Document all daily and monthly phone calls and emails.

ATTACHMENT 3: FDA Pharmacy Student Experiential Program Student Volunteer Service Agreement

Editor's note: .pdf of form to be 'paperclip attached' here.

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ATTACHMENT 4: Pharmacy Student Experiential Program eArrive Questionnaire

Editor's note: .pdf of form to be 'paperclip attached' here.

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ATTACHMENT 5: Commitment to Protect Confidential and Privileged Information

I understand that use of confidential and/or privileged information for any use other than work related to FDA official business is expressly prohibited. "FDA official business" means work or other activity that is directly related to the authorized mission and functions of FDA or any of its component centers or offices.

For purposes of this agreement, I understand "confidential information" to mean any information that is described or referenced in 21 USC 331(j) or 18 USC 1905, or any other predecisional or nonpublic information related to FDA work or activities and includes, but is not limited to, the following: proprietary data (including information or data that would be considered trade secrets within the meaning of 18 USC 1839 or 21 CFR 20.61), confidential commercial information (including the existence of an application that has not previously been publicly disclosed or acknowledged), information derived from and communicated during Agency deliberative processes, information relating to enforcement actions, and information relating to the development of regulations, guidance documents, citizen petition responses or responses to regulatory consults. I further understand "privileged information" includes, but is not limited to, all information that would fall under the scope of Article V of the Federal Rules of Evidence.

I will ask my PSEP preceptor or supervisor for guidance and direction should I have any questions regarding the above rules or if I am at any time not certain as to the

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confidentiality of any type of information. If I believe there may have been an unauthorized release of confidential and/or privileged information, I will report such breach immediately to my preceptor.

I have read and understand the content of this document and accept the responsibilities as outlined above. I understand that any unauthorized disclosure (whether intentional or inadvertent) of confidential and/or privileged information may lead to civil or criminal action. Further, I understand that FDA may report any such unauthorized disclosure of confidential and/or privileged information to my pharmacy school and state licensing authority.

I also understand that my obligations under this agreement do not end with the termination of my rotation.

I enter into this agreement willingly and with full knowledge of its scope and application.

Signed:		Date:	
Name:			
Witnessed by:		Date:	
	(PSEP Preceptor)		

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