RUTGERS
Ernest Mario School of Pharmacy

Pharmacy Law Home Study for Pharmacists and Pharmacy Technicians

"Prescription Drugs User Fee Act (PDUFA) V Reauthorization: Advancements in Drug Development and Review"

(Knowledge-Based CPE Activity)

Program Goal and Objectives

At the completion of this program, the participant will be able to explain the history and evolution of the Prescription Drug User Fee Act (PDUFA); identify the major changes in each PDUFA reauthorization and the impact on the drug development and review process and analyze the key changes in PDUFA V and the goals of the program.

Continuing Education Credit

Release Date: 08/01/2013
Expiration Date: 08/01/2015 No credit will be give after the expiration date

Fee: The fee for this educational activity is $20

Program Audience: Registered Pharmacists and Pharmacy Technicians

The Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

This program is approved for 0.150 CEUs (1.50 contact hours) law continuing education credits. In order to receive 1.50 law contact hours of CE credits, the participant must read the slides, complete the post-test questions with at least a score of 70% and complete the evaluation form. If participant fails first time, may retake the post-test questions at an additional fee of $20. Continuing education credits (paperless) can be viewed at www.MyCPEmonitor.net two weeks after passing the post-test questions. The Universal Activity Number is **0038-0000-13-047-H03-P-T**

Course Development and Review Committee

Angelo Cifaldi, R.Ph., J.D.
Adjunct Associate Professor or Pharmacy Law, Rutgers University,
Ernest Mario School of Pharmacy
Wilentz, Goldman and Spitzer Attorneys at Law
Professor and Former Dean,
Rutgers University, Ernest Mario School of Pharmacy

Course Development

Historical Overview and Road to PDUFA V
Justin Balint, PharmD
Rutgers University, Ernest Mario School of Pharmacy
Post-Doctoral Fellow
Policy and Advocacy

Enhancing Transparency and Communication
Caroline Nguyen, PharmD
Rutgers University, Ernest Mario School of Pharmacy
Post-Doctoral Fellow
Global Scientific Communications and Home Office Medical

Risk Benefit Framework
Vishal Patel, Pharm.D.
Rutgers University, Ernest Mario School of Pharmacy
Post-Doctoral Fellow
Promotion Integrity

Pediatrics: BPCA and PREA Summary
Sanchali Kasbekar, Pharm.D.
Rutgers University Ernest Mario School of Pharmacy
Post-Doctoral Fellow
Global Regulatory Sciences

Review Committee

Angelo Cifaldi, R.Ph., J.D.
Adjunct Associate Professor or Pharmacy Law, Rutgers University,
Ernest Mario School of Pharmacy
Wilentz, Goldman and Spitzer Attorneys at Law
Professor and Former Dean,
Rutgers University, Ernest Mario School of Pharmacy

Satish V. Poondi, R.Ph., Esq.
Spoondi@wilentz.com
732-855-6154
Wilentz, Goldman, & Spitzer P.A
90 Woodbridge Center Drive
Woodbridge, NJ 07095

Evelyn Hermes DeSantis, Pharm.D., BCPS
Clinical Associate Professor,
Rutgers University, Ernest Mario School of Pharmacy
Director, Drug Information Services,
Robert Wood Johnson University Hospital

Contact Person

Please contact Vickie Georgiana, Program Coordinator, should problems related to the content or functioning of the continuing education activity arise:

Email:	vjclay@pharmacy.rutgers.edu
Telephone:	848-445-6823 (8:00 am - 4:00 pm - Monday thru Friday)
Mail:	Vickie Georgiana Rutgers, The State University of New Jersey, Pharmacy Practice & Administration - Room 417E 160 Frelinghuysen Road, Piscataway, NJ 08854

Post-Test Questions

(Circle your answers on the Post-Test Answer Form on page 7)
(Mailing instructions are also on page 7)

"Prescription Drugs User Fee Act (PDUFA) V Reauthorization: Advancements in Drug Development and Review"

(Knowledge-Based CPE Activity) UAN #0038-0000-13-047-H03-P-T

Dr. Balint's Questions for "Historical Overview and Road to PDUFA V"

1. Which of the following drugs would meet the criteria for a priority review?

   I. B91X – an oncolytic used for the treatment of HER-2–positive, unresectable locally advanced or metastatic breast cancer for those who have received prior treatment and failed where no other treatment available provides enhanced survival benefit
   II. RP743 – a hypoglycemic agent with a new mechanism of action to lower blood sugar in type II diabetic patient
   III. AL987 – an androgen receptor signaling inhibitor used for castration-resistant prostate cancer who previously underwent docetaxel-based chemotherapy where few other options exist

   A. I and III
   B. II
   C. II and III
   D. I, II and III

2. Which of the following can be attributed to the success of the PDUFA program?

   A. Drug review times have fallen by more than 55% since enactment
   B. User fees have led to new government jobs in the FDA
   C. Clear and predictable performance goals have been established
   D. All of the above

3. Which of the following pieces of legislation re-authorized the user fee program and shortened the goal for standard review times from 12 months to 10 months?

   A. Bioterrorism Preparedness & Response Act
   B. FDA Amendments Act
   C. FDA Modernization Act
   D. Affordable Care and Patient Protection Act
   E. FDA Safety and Innovation Act

4. Which of the following changes did not take effect in PDUFA IV (FDA Amendments Act)?

   A. Three year limit of post-marketing surveillance activities removed.
   B. Modernization of regulatory science to handle issues such as biomarkers, patient reported outcome tools, and pharmacogenomics.
   C. Expansion of the Good Review management Practices to expedite drug review.
   D. Mandatory Advisory Committee meetings for most new drugs as part of development

Dr. Nguyen's Questions for: "Enhancing Transparency and Communication"

5. Under PDUFA V, what is the total amount of time from FDA receipt of the NDA/BLA to FDA action date?

    A. 8 months for priority and 6 months for standard review
    B. 10 months for priority and 8 months for standard review
    C. 6 months for priority and 10 months for standard review
    D. 8 months for priority and 12 months for standard reviews

6. What is the goal of the pre-submission meeting?

    A. Agree on content of complete application
    B. Preliminary discussion on need for REMS
    C. Agree on delayed submission components
    D. All of the Above

7. In what instances would the FDA communication liaison be the sponsor's primary point of contact?

    A. General questions about drug development not involving formal FDA meeting
    B. Application specific questions about drug development
    C. Communication liaison staff is never the primary point of contact
    D. Questions about drug development that require a formal meeting

8. The post-action meeting is:

    A. A required meeting to occur after approval of drug
    B. Offered to all NME NDAs and original BLAs
    C. Optional meeting to occur after FDA regulatory action other than approval
    D. A&B
    E. B&C

Dr. Patel's Questions for "Risk Benefit Framework"

9. What are the main considerations that patients will have input on?

    I. Risk
    II. Analysis of Condition
    III. Benefit
    IV. Risk Management
    V. Unmet Medical Need

    A. I
    B. II and III
    C. II and IV
    D. II and V
    E. I, II, III, and V

10. When does the FDA plan to begin execution of the risk benefit framework?

    A. End of Q4 FY2014
    B. End of Q4 FY2013
    C. End of Q3 FY2013
    D. End of Q3 FY2014

11. The risk benefit framework will change the criteria used to evaluate drugs for approval.

    A. True
    B. False

Dr. Kasbekar's Questions for "Pediatrics: BCPA and PREA Summary"

12. Which of the following is true regarding the Pediatric Research Equity Act (PREA)?

    A. Mandatory
    B. Requires studies only for indication(s) under review
    C. Exemption for orphan indications
    D. All of the above

13. The initial pediatric plan must be submitted no later than

    A. 60 days after an EOP2 meeting
    B. 30 days before an EOP2 meeting
    C. After market drug approval
    D. 60 days before an EOP2 meeting

14. Which of the following is true regarding the Best Pharmaceuticals for Children Act?
    A. Mandatory
    B. Optional
    C. Offers 6 months of exclusivity added on to patent life
    D. B&C

THE END

Pharmacy Program Post-Test Answer Form

(Circle answers and mail this page with Name Form and Evaluation Forms pgs. 8,9 and 10)

Pharmacy Law Home Study
"Prescription Drugs User Fee Act (PDUFA) V Reauthorization: Advancements in Drug Development and Review"

UAN # 0038-0000-13-047-H03-P-T
(Knowledge-based CPE activity)

This form must be completed to receive law continuing education credit. Circle your answers to the questions at the right. You can either email Post-Test Answer Form and Evaluation Form to: vjclay@pharmacy.rutgers.edu or fax to: 732-445-2533 with credit card info – fee $20

or

Mail Post-Test Answer Form, Evaluation Form and $20 check made to:

Rutgers, The State University of New Jersey
Continuing Education
Ernest Mario School of Pharmacy
160 Frelinghuysen Road, Room 417E
Piscataway, NJ 08854-8020

Circle Your Answer

1.	a	b	c	d	e
2.	a	b	c	d	e
3	a	b	c	d	e
4.	a	b	c	d	e
5.	a	b	c	d	e
6.	a	b	c	d	e
7.	a	b	c	d	e
8.	a	b	c	d	e
9	a	b	c	d	e
10.	a	b	c	d	e
11.	a	b	c	d	e
12.	a	b	c	d	e
13.	a	b	c	d	e
14.	a	b	c	d	e

The Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

This program is approved for 0.200 CEUs (2.00 contact hours) law continuing education credits. In order to receive 2 law contact hours of CE credits, the participant must read the slides, complete the post-test questions with at least a score of 70% and complete the evaluation form. If participant fails first time, may retake the post-test questions at an additional fee of $20. Continuing education credits (paperless) can be viewed at www.MyCPEmonitor.net two weeks after passing the post-test questions. The Universal Activity Number is **0038-0000-13-047-H03-P-T.**

Initial Release Date: 08/01/2013 **Expiration Date: 08/01/2015**

"Prescription Drugs User Fee Act (PDUFA) V Reauthorization: Advancements in Drug Development and Review"

UAN # 0038-0000-13-047-H03-P-T
(Knowledge-based CPE activity)

NAME FORM

Name_____
(Print only)

Check one, if applicable:

R.Ph. _____ Pharm.D. _____ Other (specify)_____

YOU MUST Provide: NABP e-Profile #_____ Date of Birth:_____

(to acquire a NABP #……. please go to: http://www.nabp.net)

Home Address_____

City_____State_____ Zip Code_____

Telephone
(work)_____(home)_____

Email_____

Credit Card Information

Name of Credit Card:_____ Credit Card #:_____

Expiration Date:_____ 3 or 4 digit code on back of card:_____

PROGRAM EVALUATION

(Circle your rating and mail with Post-Test Answer Form pg. 5)

Pharmacy Law Home Study

"Prescription Drugs User Fee Act (PDUFA) V Reauthorization: Advancements in Drug Development and Review"

UAN # 0038-0000-13-047-H03-P-T
(Knowledge-based CPE activity)

Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy would appreciate your comments on the quality of this educational activity. Please rate the following by using a 5-point grading system, with 1 being the lowest rating (strongly disagree/poor) and 5 being the highest rating (strongly agree/excellent).

Did this program meet the following learning objectives?

1. Discuss key changes in the fifth authorization of Prescription Drug User Fee Act (PDUFA)?

   1 2 3 4 5

2. Discuss the evolution of Prescription Drug User Fee Act (PDUFA)?

   1 2 3 4 5

3. Summarize updates to Federal Drug Agency's (FDA) approach to transparency and communication.

   1 2 3 4 5

4. Recognize the development and implement of the risk-benefit framework.

   1 2 3 4 5

5. Explain changes to the pediatric drug development process.

   1 2 3 4 5

What aspects of this activity were of most interest to you?

_____

Do you have any comments or suggestions for this or future activities?

_____

Thank you for your interest in
Rutgers, The State University of New Jersey,
Ernest Mario School of Pharmacy