**Activity Outline**
**FDA Drug Topics: Nitrosamine Impurities in Drugs: What Health Care Professionals Need to Know**
**May 5, 2020**
**FDA**

**Activity Coordinator:**
Lesley Navin (Lesley.Navin@fda.hhs.gov), Kimberly DeFronzo (Kimberly.Defronzo@fda.hhs.gov), Kara Burke (Kara.Burke@fda.hhs.gov),

**Series Description**

This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, certified public health professionals, other health care professionals, and students, to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety.

**Lecture Description**
This educational activity will provide an overview of nitrosamine impurities identified in several prescription and over-the-counter drug products. The presentation will include background information on nitrosamines, a discussion of pharmaceutical quality, FDA's role in protecting the public, and an overview of public outreach and engagement as it relates to this issue.

**References**

- “Impurity Identification and control,” Deborah F. Johnson, Ph.D., presentation in DIA-USFDA-EMA-EDQM workshop on API Manufacturing and Supply Chain Integrity, November 2019.
- Information about Nitrosamine Impurities in Medications: www.fda.gov/Nitrosamines.
- Recalls, Market Withdrawals, & Safety Alerts: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts.
- FDA Drug Shortages: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

**Series Objectives**

- Explain how to utilize FDA’s drug information, medication safety resources, and regulatory guidance, to improve delivery of patient care and optimize outcomes.
- Describe and inform health care providers of recent labeling, policy and regulatory changes which would impact prescribing and medication management to optimize patient care.

**Learning Objectives** After completion of this activity, the participant will be able to:

- Describe FDA’s role in helping to ensure the quality of drugs marketed in the U.S.
- Discuss the drug classes that have been affected by nitrosamine impurities.
- Identify 3 ways to obtain information about medications recalled due to nitrosamine impurities.

**Target Audience**
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, cph - certified public health, and physician assistants.

**Agenda**

**Lecture 1 May 5, 2020**

| Time | Topic | Speaker |
|---|---|---|
| 1:00 - 2:00 PM | Nitrosamine Impurities in Drugs: What Health Care Professionals Need to Know | Jacqueline LeeHoffman, Pharm.D.<br>Sonia Kim |

**Continuing Education Accreditation**


In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.


This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

**CME**

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**CPE**

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-20-006-L04-P, and ACPE Universal Activity Number JA0002895-0000-20-006-L04-T for 1.00 contact hour(s).

**CNE**

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

**AAPA**

This activity is designated for 1.00 AAPA Category 1 CME credits. FDA Center for Drug Evaluation and Research has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. PAs should only claim credit commensurate with the extent of their participation.

**CPH**

Up to 1.00 CPH Recertification Credits may be earned at this event.

**Requirements for Receiving CE Credit**

**Physicians, physician assistants, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME:**participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

**Important Note regarding completion of evaluations and receiving credit**
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians, physician assistants, and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

**Disclosure**

**Faculty**

- Kim, Sonia, Pharmacist, FDA - nothing to disclose
- LeeHoffman, Jacqueline, Pharm.D., Safety Regulatory Project Manager, FDA/CDER/OND/DGIEP - nothing to

disclose

**Planning Committee**

- Burke, Kara, PharmD, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- Cao, Christian, MPAS, PA-C, Safety Evaluator Team Leader, FDA/CDER/OSE/DPV - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Kapoor, Rama, MD, Medical Officer, FDA - nothing to disclose
- Navin, Lesley, RN, MSN, Consumer Safety Officer, FDA/CDER/DDI - nothing to disclose

**CE Consultation and Accreditation Team**

- Lisa Thompson, MSHA, MBA, CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

**Registration Fee and Refunds**
Registration is complimentary, therefore refunds are not applicable.