NABP
National Association of Boards of Pharmacy

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey "Al" Carter, Executive Director/Secretary

DATE: December 5, 2024

RE: *FDA Drug Topics: An Update on Transmucosal Buprenorphine and Dental Caries* – December 10, 2024

Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research will host a webinar on December 10, 2024, from 1-2 PM ET, titled, *FDA Drug Topics: An Update on Transmucosal Buprenorphine and Dental Caries.* Learning objectives for this session include the following:

- Discuss the national opioid crisis, opioid use disorder, and available treatments.
- Describe cases of dental caries with the use of transmucosal buprenorphine-containing products.
- Review FDA's framework for updating product labeling and explain FDA's findings and the resulting regulatory action.
- Summarize how health care providers can help mitigate these adverse events.

This session is intended for pharmacists, pharmacy technicians, students, and other health care professionals. Additional information, including the registration link, is attached.

cc: NABP Executive Committee

Please direct your comments or questions via email to DDIWebinars@fda.hhs.gov.

FDA Drug Topics: An Update on Transmucosal Buprenorphine and Dental Caries

Tuesday, December 10, 2024

Time: 1:00 PM – 2:00 PM (ET)

Register

After registering, you will receive a calendar invitation with details on how to join the online ZOOM meeting.

An email will be sent to all participants by the next business day with instructions on how to claim CE and a copy of the presentation slides.

Activity Outline

Description: This series of educational webinars is designed to aid physicians, physician assistants, nurse practitioners, 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. In this webinar, we will highlight the regulatory action taken by FDA regarding a post-market safety signal of transmucosal buprenorphine products and dental caries. The audience will gain knowledge on the science behind this action, as well as increase their awareness of the national opioid crisis, treatments for opioid use disorder, and FDA's regulatory authority for addressing safety issues in drug labeling. Upon completion of the activity, healthcare providers will leave with an improved understanding of these adverse events and be better equipped to inform patients.

References:

- Treatment for Opioid Use Disorder: Population Estimates — United States, 2022 | MMWR
- Suzuki, J., L. Mittal, and S. B. Woo. 2013. 'Sublingual buprenorphine and dental problems: a case series', Prim Care Companion CNS Disord, 15.
- Suzuki, J., and E. M. Park. 2012. 'Buprenorphine/naloxone and dental caries: a case report', Am J Addict, 21: 494-5.
- Buprenorphine: Drug Safety Communication - FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain
- Etminan, Mahyar, Ramin Rezaeianzadeh, Abbas Kezouh, and Kevin Aminzadeh. 2022. 'Association Between Sublingual Buprenorphine-Naloxone Exposure and Dental Disease', JAMA, 328: 2269-71.
- Barus, R., F. Montastruc, C. de Canecaude, H. Bagheri, A. Sommet, and M. Lapeyre-Mestre. 2023. 'Sublingual/Buccal buprenorphine and dental problems: a pharmacovigilance study', Expert Opin Drug Saf, 22: 1283-87.

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 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:

- Discuss the national opioid crisis, opioid use disorder, and available treatments.
- Describe cases of dental caries with the use of transmucosal buprenorphine-containing products.
- Review FDA's framework for updating product labeling and explain FDA's findings and the resulting regulatory action.
- Summarize how healthcare providers can help mitigate these adverse events.

Target Audience: This activity is intended for physicians, physician assistants, nurse practitioners, nurses, pharmacists, pharmacy technicians, certified public health professionals, other health care professionals, and students.

Schedule:

1:00 pm - 2:00 pm – **FDA Drug Topics: An Update on Transmucosal Buprenorphine and Dental Caries** presented by CDR Mark Liberatore, PharmD, RAC, Deputy Director for Safety of the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) in FDA's Center for Drug Evaluation and Research.

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 and physician assistants 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 JA0002895-0000-24-100-L08-P, and ACPE Universal Activity Number JA0002895-0000-24-100-L08-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:

All learners claiming credit must attest to their attendance and complete all required activity evaluations in the FDA CE Portal (ceportal.fda.gov) within 14 days after this activity ends. Upon completion, learners may view or print their statement of credit.

For those of you who are pharmacists or pharmacy technicians: The FDA CE Team will report your credit to the National Association of Boards of Pharmacy—otherwise known as "NABP"—provided you add your NABP ID and date of birth to your profile in the FDA CE Portal. The only official Statement of Credit is the one you pull from CPE Monitor. If you do not see your credit reflected on the CPE Monitor after 45 days of attestation, please contact FDACETeam@fda.hhs.gov. The CPE Monitor sets a strict 60-day limit on uploading credits.

Disclosure:

Faculty:

- Liberatore, Mark, PharmD, RAC, Deputy Director for Safety, FDA/CDER/OND/ON/DAAP - 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/CDER/OND/OID/DAI - nothing to disclose
- Nguyen-Chu, Thanh Tam, PharmD, BCPS, Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- Paraoan, Dianne, MPH, RN, Associate Director for Regulatory Affairs, FDA/CDER/OMP - nothing to disclose

CE Consultation and Accreditation Team:

- Littlefield, Jr, Kenneth P., Training Specialist, FDA/CDER/OEP/DLOD - nothing to disclose
- Bryant, Traci, M.A.T., Lead Training Specialist, FDA/CDER/OEP/DLOD - nothing to disclose
- Wood, Sara, Accreditation Program Administrator, CECAT, FDA/CDER/OEP/DLOD - nothing to disclose

If you are unable to attend this webinar, please note that a recording will be uploaded to our webpage about 5-7 business days after the event has concluded. Listening to this recording will not offer CE. If interested in CE, please listen to our past webinar recordings on our website under "Home Study CE Webinars".

Registration Fees and Refunds: Registration is complimentary therefore refunds are not applicable.

Please direct your comments or questions via email to DDIWebinars@fda.hhs.gov.

To learn more about future dates and registration, please visit: www.fda.gov/DDIWebinars.