Activity Outline
FDA Grand Rounds:
Rapid On-Site Detection of Unlawful Substances in Dietary Supplements Using Ion Mobility Spectrometry

September 8, 2016
12:00 PM-1:00 PM

Series Description
The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Description
The increased availability and use of dietary supplements among consumers has been accompanied by an increased frequency of adulteration of these products with undeclared pharmaceutical substances and unapproved ingredients. The presence of these adulterated products in the marketplace is a worldwide problem and their consumption poses health risks to consumers. In response, the FDA has developed a program to evaluate rapid screening tools to be used in assessing the quality and safety of imported dietary supplements. One of the techniques that the Division of Pharmaceutical Analysis (DPA) has developed for the program is ion mobility spectrometry (IMS), a rapid, reliable screening tool that requires minimal sample preparation and produces results in less than a minute. The FDA is currently exploring the use of IMS instruments at US ports of entry to test products labeled as dietary supplements that are suspected of containing undeclared Active Pharmaceutical Ingredients (APIs) or unapproved new dietary ingredients. This presentation will describe the development of IMS screening methods for product quality surveillance as well as discuss the efforts used by the agency to deploy the IMS instruments in the field for on-site testing. IMS screening can quickly identify violative products and assist the FDA in removing these products from the market place. Also, the FDA can issue alerts and bulletins in a timely manner warning consumers of potential hazards associated with the consumption of adulterated supplements.

References

1. Gryniewicz, C. M., Reepmeyer, J. C., Kauffman, J. F., and Buhse, L. C. "Detection of Undeclared Erectile Dysfunction Drugs and Analogues in Dietary Supplements by Ion Mobility Spectrometry" *Journal of Pharmaceutical and Biomedical Analysis* 2009, 49, 601-606.

2. Dunn, J. D.; Gryniewicz-Ruzicka, C. M.; Mans, D. J.; Mecker-Pogue, L. C.; Kauffman, J. F.; Westenberger, B. J.; Buhse, L. F. "Qualitative Screening for Adulterants in Weight Loss Supplements by Ion Mobility Spectrometry", *Journal of Pharmaceutical and Biomedical Analysis* 2012, *71*, 18-26.

Series Objectives:
1. Discuss the research conducted at the FDA
2. Explain how FDA science impacts public health

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

1. Identify the types of dietary supplements most often adulterated with active pharmaceutical ingredients.

2. Describe ion mobility spectrometry and explain how the FDA is using this technique to assess the quality and safety of imported products.

Target Audience
This activity is intended for physicians, pharmacists, nurses and other scientists within the agency and external community.

Schedule

Date/Time/Place	Lecture Title	Lecturer
Thursday, September 8, 2016 12:00 pm –1:00 pm	Rapid On-Site Detection of Unlawful Substances in Dietary Supplements Using Ion Mobility Spectrometry	Connie M. Gryniewicz-Ruzicka, Ph.D.

Continuing Education
The Food and Drug Administration, Center for Drug Evaluation and Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

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

The FDA-Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-16-073-L04-P). This program meets the criteria for 1 contact hour(s) of pharmacy education.

This activity is a knowledge - based activity**.** These CE activities are primarily constructed to transmit knowledge (i.e., facts). The facts must be based on evidence as accepted in the literature by the health care professions.

FDA, Center for Drug Evaluation and Research is an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
This 1 contact hour Education Activity is provided by FDA, Center for Drug Evaluation and Research. Each nurse should claim only the time that he/she actually spent in the educational activity.

Requirements for receiving CE credit
Physicians, pharmacists, nurses and those claiming non-physician CME: attendance is verified by a sign-in sheet and completion of the final activity evaluation. For multi-day activities, participants must sign in every day. Final activity evaluations must be completed within two weeks after the activity.

Pharmacy participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. 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.

Statements of Credit
Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty
Connie M. Gryniewicz-Ruzicka, Ph.D., Research Chemist, OMPT/CDER/OPQ/OTR/DPA has nothing to disclose

Planning Committee
Emannuel Fadiran, PhD, RPh, Intramural Research Program Director, FDA/OC/OWH, has nothing to disclose
Eileen Parish, MD, Medical Officer, FDA/OC/OCS/OSPD, has nothing to disclose
Leslie Wheelock, MS, RN, Director OSPD, FDA/OC/OCS/OSPD, has nothing to disclose

CE Consultation and Accreditation Team
Traci Bryant, B.A., M.A., Education Specialist, FDA/CDER/OEP/DLOD, has nothing to disclose
Virginia Giroux, MSN, ARNP, CE Program Administrator, CDER/DLOD, has nothing to disclose
Rokhsareh Shahidzadeh, MSN, RN, Regulatory Health Education Specialist, DLOD/CDER, has nothing to disclose
Karen Zawalick, CE Team Leader, FDA/CDER/OEP/DLOD, has nothing to disclose

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

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the lectures (verified by a sign-in sheet).

Initial Release Date: September 8, 2016

Registration and Remote Access Instructions:

To register for the webcast, please click the link below and click the link that says "please click here to register." Then follow the instructions. After you register you must use the same link below to access the live webinar by logging in with your username and password which you create when you register.

Access link:

https://collaboration.fda.gov/grandroundsregs982016/event/login.html

For technical assistance please contact Jeffery Rexrode at Jeffery.Rexrode@fda.hhs.gov.

*The on-line presentation provides reasonable accommodation for individuals with disabilities.