Activity Outline

FDA Grand Rounds:
Characterization of nanomaterials in FDA regulated products

January 12, 2017

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.

Session Description

Production and application of nanoparticles in consumer products is at an all-time high due to the emerging field of nanotechnology. Direct detection and quantification of trace levels of nanoparticles within consumer products is very challenging and problematic. Inorganic nanoparticles such as gold, silver, titanium dioxide and zinc oxide, are used in various consumer products such as dietary supplements and sunscreens. Characterization of inorganic nanoparticles includes quantification of metallic content, size based separation, size determination and speciation based on oxidation state. Liposomes are prime examples of organic nanomaterials used in drug delivery systems and dietary supplements. Encapsulated active ingredient content, lipid profile, size and zeta potential are determined in the characterization of liposomal products. This presentation will describe the developed methodology for characterization of inorganic and organic nanoparticles using various microscopic techniques, light scattering, size-based separation methodology, elemental analysis and mass spectrometry.

References

1. Thilak K. Mudalige, Haiou Qu and Sean W. Linder "An Improved Methodology of Asymmetric Flow Field Flow Fractionation Hyphenated with Inductively Coupled Mass Spectrometry for the Determination of Size Distribution Gold Nanoparticles in Dietary Supplements" J. Chromatography A , 2015, 1420, 92-97
2. Venu Gopal Bairi, Jin-Hee Lim, Ivan Quevedo, Thilak K. Mudalige, and Sean W. Linder, "Portable XRF Spectroscopy as a Rapid Screening Technique for Analysis of TiO2 and ZnO in Sunscreens" Spectrochimica Acta Part B, 2016, 116, 21–27.
3. Jin-Hee Lim, Patrick N. Sisco, Thilak K. Mudalige, Germarie Sánchez-Pomales, Paul C. Howard, and Sean W. Linder, "Detection and Characterization of SiO2 and TiO2 Nanostructures in Dietary Supplements" J. Agric. Food Chem., 2015, 63, 3144-3152.
4. Haiou Qu, Thilak K. Mudalige, and Sean W. Linder, "Capillary Electrophoresis/Inductively-Coupled Plasma-Mass Spectrometry: Development and Optimization of a High Resolution Analytical Tool for the Size-Based Characterization of Nanomaterials in Dietary Supplements" Anal. Chem., 2014, 86, 11620.

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. Explain Nanotechnology and nanomaterials
2. Describe FDA regulated products that contain nanomaterials
3. Discuss the characterization methodologies available for nanomaterials in products
4. Examine the advantages of each characterization methodology

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, January 12, 2017 12:00 PM-1:00 PM	FDA Grand Rounds: Characterization of nanomaterials in FDA regulated products	Thilak Kumara Mudalige, PhD

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. 0601-0000-16-124-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
Thilak Kumara Mudalige, PhD, Research Chemist – Nanotechnology, Office of Regulatory Affairs, Arkansas Regional Laboratory, has nothing to disclose.

Planning Committee
Virginia Giroux, MSN, ARNP, CE Program Administrator, CDER/DLOD, has nothing to disclose
Emannuel Fadiran, PhD, RPh, Intramural Research Program Director, FDA/OC/OWH, has nothing to disclose
Rokhsareh Shahidzadeh, MSN, RN, Regulatory Health Education Specialist, DLOD/CDER, 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
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: January 12, 2017

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/grandroundsregistrationjan122017/event/registration.html

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

Reasonable Accommodations
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