



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Food and Drug Administration/Drug Information Association Oligonucleotide-Based Therapeutics Conference 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research, in cosponsorship with the Drug Information Association (DIA), is announcing a meeting entitled "FDA/DIA Oligonucleotide-Based Therapeutics Conference 2015" (FDA/DIA 2015 conference). The purpose of the meeting is to discuss advances, safety, and challenges in the field of oligonucleotide-based therapeutics.

DATES: The meeting will be held on September 9 to September 10, 2015, from 7 a.m. to 5 p.m. and September 11, 2015, from 7 a.m. to 12 noon.

ADDRESSES: The meeting will be held at the Grand Hyatt Washington, 1000 H St. NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Meredith Kaganovskiy, Drug Information Association (DIA), 800 Enterprise Rd., Horsham, PA, 19044, 215-442-6117, FAX: 215-293-5923, email: Meredith.kaganovskiy@diaglobal.org; or Robert T. Dorsam, Food and Drug

Administration, Center for Drug Evaluation and Research (CDER), 10903 New Hampshire Ave., Silver Spring, MD, 20993-0002; 301-796-1623, email: robert.dorsam@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Oligonucleotide therapeutics constitute a diverse and evolving class of drug products that are being developed for a wide variety of indications. The FDA/DIA 2015 conference is a forum where regulators, academics, and members of industry will discuss the advances, challenges, and opportunities in the field of oligonucleotide therapeutics. This is the sixth meeting in approximately eight years where attendees will discuss oligonucleotide therapeutics in clinical, nonclinical, and chemistry tracks. The meeting will provide updates on advancements in this field, and will also present time for stakeholders to discuss challenges in the development and regulation of oligonucleotide therapeutics. Topics will be addressed using presentations, panel discussions, case studies, and a poster session to facilitate discipline-specific and multidisciplinary discussions. The goal of the meeting is to provide a current view of oligonucleotide therapeutics and foster advancement in the field through discussions among regulators, academics, and industry members.

II. Registration and Accommodations

A. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs of facilities, meeting materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at <http://www.diaglobal.org/>. (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site

after this document publishes in the Federal Register.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	\$1,350
Charitable Nonprofit/Academic	\$675
Government	\$405

B. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Grand Hyatt Washington are eligible for a reduced rate of \$209, not including applicable taxes. This rate is available for a limited number of rooms. To receive the reduced rate, hotel reservations must be made with onPeak and not directly with the hotel. Contact information for onPeak is as follows: Toll free in the United States 1-855-355-0302 or 1-212-532-1660. When calling, please select option 1 for “Hotel Reservations,” and inform the phone agent that you are making a reservation for Event #15011.

If you need special accommodations due to a disability, please contact Meredith Kaganovskiy (DIA) or Robert. T. Dorsam (FDA) (see FOR FURTHER INFORMATION CONTACT).

Dated: August 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-21639 Filed: 9/1/2015 08:45 am; Publication Date: 9/2/2015]