Side event application / Formulaire de demande de réunion parallèle

Contact

| Name/Nom: | Lou Valdez, Associate Commissioner, U.S. Food and Drug Administration Gabrielle Lamourelle, HHS Office of Global Affairs | Date of application/Date de la demande: | 3/29/19 |

Delegation(s)/Délégation(s): United States of America (cosponsors to be confirmed)

Telephone, Email/Téléphone, courriel: | Marylou.valdez@fda.hhs.gov | +1-301-335-5562 | Gabrielle.Lamourelle@hhs.gov | +1-202-260-6034 |

Concept

Description of proposed side event, including objective, expected results, proposed programme and speakers* / Description de la réunion parallèle proposée, y compris les objectifs, les résultats attendus, l'ordre du jour et les orateurs* :

**TOPIC:** “Celebrating Regulatory Contributions to Ensuring the Safety and Quality of HIV/AIDS Drugs and the Resulting Impacts in the Fight Against HIV/AIDS”

May 2019 marks the 15th anniversary since the U.S. Food and Drug Administration (FDA) announced its FDA Approved and Tentatively Approved Antiretrovirals in Association with the President’s Emergency Plan for AIDS Relief (PEPFAR) initiative. With 212 products approved so far, the initiative has helped expand the number of therapies available for purchase and use around the globe, fostered confidence in their safety and quality, and generated cost savings that enable more people to receive treatment. This initiative, along with the innovation of new therapies and key regulatory efforts by partner countries, multilateral organizations, and international partners, has increased access to safe and high-quality HIV/AIDS drugs around the globe (especially in PEPFAR-recipient countries), impacting health systems and strengthening the role and functioning of regulatory systems as the global community tackles the public health scourge of HIV/AIDS.

This side event highlights both the important role of regulatory engagement (such as FDA in the PEPFAR program) and elevating the implementing governments’ roles in regulatory systems strengthening and programmatic improvements.

**OBJECTIVES:** This event aims to raise awareness and appreciation of regulatory contributions to addressing the HIV epidemic through ensuring the safety and quality of HIV/AIDS drugs. A panel of experts representing Ministries of Health, multilateral institutions and international partners will discuss the ways in which regulatory systems efforts have helped expand the number of therapies available for purchase and use around the globe, fostered confidence in their safety and quality, and generated cost savings that enable more people to receive treatment. Expected results include a renewed commitment to continue to work together across the relevant global institutions and programs to improve the lives of millions of people living with and affected by HIV/AIDS, especially through safe, quality therapies.

**FORMAT:** panel presentation and dialogue with experts representing Ministries of Health, multilateral institutions and international partners. Presentations may address:

- **Proposed Program Overview (Total Time 90 Minutes)** –*speakers to be confirmed*
  - Facilitator: U.S. Secretary of Health and Human Services (TBC)

  - Introduction and welcome to panel session
  - Bilateral donor perspectives:
    - Ambassador Debbie Birx, U.S. Global AIDS Coordinator
    - Health Minister(s) on bilateral and multilateral engagement, such as through the Global Fund to Fight AIDS, TB and Malaria
- **Recipient country efforts:**
  - Health Minister(s) on national and regional drug registrations work
  - Health Minister(s) on program transitions to national government purchasing of ARVs

- **Multilateral perspectives:**
  - Global Fund to Fight AIDS, TB and Malaria
  - WHO leadership on WHO's Collaborative Procedure supporting lower resource countries' capacity to review applications for approval and entry into their markets
  - UNAIDS

- **Industry Representative** who has participated in the FDA Tentative Approval Program

### Event details / détails de la réunion

<table>
<thead>
<tr>
<th>Date</th>
<th>Wednesday 5/21</th>
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<tr>
<td>Time/Heure</td>
<td>evening session</td>
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**Expected number of participants/Nombre de participants attendus:** 100-250

**Exact title of the event/Titre exact de la réunion:** "Celebrating Regulatory Contributions to Ensuring the Safety and Quality of HIV/AIDS Drugs and the Resulting Impacts in the Fight Against HIV/AIDS"

### Interpretation/Interprétation

Interpretation may be provided in the official languages and the estimated costs are as follows: 2 languages: 2568 CHF; 3 languages: 5136 CHF; 6 languages: 11985 CHF.

L'interprétation peut être assurée dans les langues officielles aux coûts estimés suivants : 2 langues-2568 CHF; 3 langues : 5136 CHF; 6 langues : 11985 CHF.

<table>
<thead>
<tr>
<th>Are interpretation services requested? / L'interprétation est-elle requise ?</th>
<th>Yes/Oui ☑</th>
<th>No/Non ☐</th>
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<td>(If yes, which languages)?(Si oui, en quelle langue)</td>
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<td>English/Anglais ☑ French/Français ☑ Russian/Russe ☑ Spanish/Espagnol ☐ Chinese/Chinois ☐ Arabic/Arabe ☐</td>
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<td>Other language/autre langue:</td>
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### Invoice to be sent to/ Facture à envoyer à:

**Name/Nom** Office of International Programs, U.S. Food and Drug Administration, attention: Lou Valdez

10903 New Hampshire Ave, Silver Spring, MD 20993

FDA White Oak Bldg 32, Room 3424

**Postal address/Adresse postale:**

**E-mail/Courriel** marylou.valdez@fda.hhs.gov

### Room Layout/Aménagement des salles

Due to type of furniture and technical equipment in the room, the layout of the rooms cannot be changed. For information regarding the location and layout of rooms at the Palais des Nations, please see: [http://www.unog.ch/80256EE60057CB67/(httpPages)/BAE3AF717207A5AF80256EF80049C552?OpenDocument](http://www.unog.ch/80256EE60057CB67/(httpPages)/BAE3AF717207A5AF80256EF80049C552?OpenDocument)
Le type de mobilier et les installations techniques dans les salles ne permettent pas de modifier l’aménagement de celles-ci. Pour tout renseignement sur l’emplacement ou la disposition des salles au Palais des Nations voir le lien : http://www.unog.ch/80256EE60057CB67/(httpPages)/BAE3AF717207A5AF80256EF80049C5527OpenDocument

**Badges/ Badges d’accès**

WHA side events are for participants of the WHA and, as such, panelists and participants should be drawn from those participating in the Health Assembly.

Les réunions parallèles sont réservées aux participants de l’Assemblée; Les orateurs de ces réunions doivent donc être choisis parmi ceux-ci.

Please complete the form and send it to / Merci de remplir le formulaire et de l’envoyer à

hqgoverningbodies@who.int

by 29 March 2019