Notice on holding the Second China International Medical Device Regulatory Forum (CIMDR) and Workshop on Medical Device Pre-market Evaluation

In order to strengthen the publicity of China medical device administration regulations and policies, promote exchange and cooperations among international medical device administration and evaluation authorities, standardize enterprises' operation, boost communications between enterprises and governments and enterprises themselves, push forward application of new technical standards and technological achievements, further improve safety and efficiency of medical devices, and, with SFDA's approval, China Center for Pharmaceutical International Exchange will hold the second CIMDR from June 7, 2011 to June 10, 2011.

Moreover, in order to satisfy the need of many medical devices manufacturers in better understanding the international pre-market authorization regulations, such as application and approval procedures and technical review requirements, a workshop on medical device pre-market evaluation will be held on June 11 as a supplementary session of the forum.

Representatives from China and foreign medical device supervision departments, GHTF, medical device technical review institutions at home and abroad, standardization institutions and medical device enterprises will give speeches and interact on the CIMDR.

We look forward to your participation!

China Center for Pharmaceutical International Exchange (CCPIE)

Mar 2, 2011

Preliminary Scheme

Ⅰ **Time and Venue of the second CIMDR:**
Time: June 7, 2011-June 10, 2011
(June 7: all day registration, June 8, 9, 10: Forum)
Venue: Beijing Jiuhua Spa & Resort

Ⅱ **Forum:**

Plenary Meeting

Morning of June 8:
Opening Ceremony --- Introduction of China Medical Device Supervision and Administration Regulations
By SFDA Officials and other related departments and bureaus

Afternoon of June 8, morning of June 9:
Introduction of International Medical Device Supervision Regulations and Medical Device Standards
By Medical device supervision departments of all countries; Foreign medical device standardization organizations; China medical device standard administration organizations and related technical committees.

Sub-forums

Afternoon of June 9, full day of June 10:
1) Imaging Devices Forum
Technical development, evaluation and approval administration, clinical trial requirements, standard and testings, quality system, risk management, adverse event monitoring and handling of CT, X-ray device, ultrasonic and magnetic resonance products.

2) Cardio-cerebral Devices Forum
Technical development, evaluation and approval administration, clinical trial requirements, standard and test, quality system, risk management, adverse event monitoring and handling of pacemaker, defibrillator, artificial heart valve, cardiovascular stent, catheter, closure device etc. and related biological materials.

3) Orthopaedics and Surgical Devices Forum
Technical development, evaluation and approval administration, clinical trial requirements, standard and test, quality system, risk management, adverse event monitoring and handling of spine, joint, trauma and surgical device products etc.

4) Ophthalmic and Visual Optics Devices Forum
Technical development, evaluation and approval administration, clinical trial requirements, standard and test, quality system, risk management, adverse event monitoring and handling of contact lens, intraocular lens, eye care, ophthalmic surgical device, optometry products and materials.

5) In-vitro Diagnostic Devices Forum
Technical development, evaluation and approval administration, clinical trial requirements, standard and test, quality system, risk management, adverse event monitoring and handling of in-vitro diagnostic reagent, equipment, home-use testing device etc.

6) Odontological Devices Forum
Technical development, evaluation and approval administration, clinical trial requirements, standard and test, quality system, risk management, adverse event monitoring and handling of dental chair, dental surgical device, denture, dental implant etc and materials.

7) Drug-device Combination Products Forum
Technical development, evaluation and approval administration, clinical trial requirements, standard and test, quality system, risk management, adverse event monitoring and handling of drug-device combination products.

8) Medical Macromolecule Products and Medical Consumables Forum
Technical development, evaluation and approval administration, clinical trial requirements, standard and test, quality system, risk management, adverse event monitoring and handling of transfusion system, injector, blood bag, blood collector, dialyzer, dressings, medical package material, medical consumables.

Ⅲ **Workshop on Medical Device Pre-market Evaluation**

I.Time and Venue
June 11, 2011, Beijing Jiuhua Spa & Resort

II.Content
Reports of SG 1 of GHTF, reports and technical exchanges of domestic and foreign medical device supervision and technical evaluation institutions

Registration Information

Location of the Forum

District16, JiuHua Hotel
Xiaotangshan, Changping, Beijing, China
Zip Code: 100211
Tel：010-61782288
Web: http://www.jiuhua.com.cn

Conference Language

English and Chinese Mainly; all venues are in foreign language simultaneous interpretation.

Registration Fee

RMB4000 Yuan before May 15
RMB5000 Yuan after May 15

Registration Procedures

1. Login China International Medical Device Regulatory Forum
   web site:http://www.cimdr.com and click the online registration button；or login http://www.ccpie.org web site and open China International Medical Device Regulatory Forum page , enter the English interface and click the online registration button —— complete and upload the registration information form, handle remittance and fax remittance voucher to the Forum Secretariat: 010-82212857 (please indicate in the postscript CIMDR2011 and the registrant name).
2. The Secretariat will, after receipt of your remittance and registration information, send you a short message within 7 working days to confirm your registration. After receiving the confirmation message, you can go to the website to print the registration confirmation letter. If you do not receive the short confirmation message, please contact the Secretariat.
3. Field registration time: 9:00-20:00, Jun.7, 2011
   (In order to guarantee hotel rooms, facilitate registration and avoid field congestion on the registration day (Jun. 7), it is strongly recommended that you register beforehand.)
4. Please hold your registration confirmation letter to check in at the registration desk at Zone 16, Jiuhua Hotel, Beijing, receive forum materials, and handle accommodation procedures.

Registration Fees Delivery

Bank transfer to:
BANK OF COMMUNICATIONS HAIDIAN BRANCH
Account Name:
Asia-Med (Beijing) Exhibition & Conference Services Co.,Ltd
Account：110060576018150017317
ADD：NO.16 SUZHOU ST.,HAIDIAN DISTRICT,BEIJING

Cancellation

When a registered representative desires cancellation, please inform the secretariat in written form before May 15, 2011 for refund. The paid registration fee will be returned after deducting a handling charge of 200 yuan. Application for refund submitted after May 15, 2011 will not be accepted.

Traffic

Take subway from downtown area and get off at Tiantongyuan station, and then take a taxi to Jiuhua Hotel (about 10km), or take a taxi from downtown area to Jiuhua Hotel directly (the whole distance is over 20km, depending on the place you start with). The Organizing Committee will arrange shuttle bus service on June 7. Details of shuttle bus arrangements will be announced on the website before the Forum.

Return air ticket booking

Return tickets can be purchased at Jiuhua business center.

Volunteer Supporting

Please contact the Forum Secretariat for volunteer supporting arrangement.

Contact: Ms. Sabrina Liu：0086-10-82212866 ext 6010
Mr. Ma Zheng：0086-10-82212871
Ms.Xia Tiantian:0086-82212866 ext 6016
Ms. Shi Hui: 0086-10-82212866 ext 6015
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Registration Form

The Second China International Medical Device Regulatory Forum (CIMDR) and Workshop on Medical Device Pre-market Evaluation

Please login http://www.cimdr.com or http://www.ccpie.org to make online registration. In case of internet inconvenience, please complete this form and fax to the Secretariat: 010-82212857.

Name:_____ Gender:_____

Organization:_____ Title:_____

Address:_____ Zip:_____

Tel:_____ Fax:_____

Mobile:_____ E-mail:_____

Registration Fee

☐4000 Yuan before May 15	☐5000 Yuan after May 15

(Meals and forum materials are included)

Accommodation: (enjoy the forum discount price, at your own expense)

Room type	Forum Discount Price	Published Price
Standard room,JiuHua Hotel, 3 star level (District 9)	☐280	420
Standard room, JiuHua Hotel, 4 star level (District 15)	☐420	700
Single room, JiuHua Hotel, 4 star level (District 15)	☐420	700
Executive suite, JiuHua Hotel, 4 star level (District 15)	☐960	1320
Standard room, JiuHua Hotel, 5 star level (District 16)	☐480	840
King-size-bed room, JiuHua Hotel, 5 star level (District 16)	☐480	840
Business suite, Jiuhua Hotel, 5 star level (District 16)	☐1080	1440

Arrival Date:_____ Departure Date :_____

The Organizing Committee will arrange rooms according to booking order and room availabilities, but does not guarantee the type of rooms. The Organizing Committee will not accept earnest money. When you wish to make a change on your reservation, be sure to notify the Secretariat in writing.

Please return this form by fax or e-mail, or mail to:

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