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Kamla Nehru College of Pharmacy

Borkhedi (gate), Butibori, Nagpur-441 108 (M.S.)

One Day Seminar on "Strategies for Regulatory and Intellectual Property Challenges" organized by Kamla Nehru College of Pharmacy, Butibori, Nagpur

One day seminar on "Strategies for regulatory and intellectual property challenges" organized by Kamla Nehru College of Pharmacy, Butibori, Nagpur on June 27th, 2016. The seminar was organized for teachers and PG students.

The seminar was inaugurated by Dr. Sudhir N. Umathe, Principal, Kamla Nehru College of Pharmacy, Butibori, Nagpur. The welcome address was delivered by Mr. Mangesh D. Godbole , Assistant Professor and preamble was given by Ms. Disha M. Dhabarde, Assistant Professor, Kamla Nehru College of Pharmacy, Nagpur.

The inaugural function was followed by two long sessions conducted Dr. Sunil V. Gupta, Research and Development Manager, Zim Laboratories Pvt. Ltd., Kalmeshwar, Nagpur.

In a two long sessions, Dr. Sunil V. Gupta focuses on following points:

- New Drug Application contains full reports of investigations of safety and effectiveness and filed under section 505(b)(1).
- Intellectual property and New Drug Application are independent of each other. The patent term restoration cannot exceed 5 yrs in length and cannot extend beyond 14 yrs after New Drug Application approval.
- Patent information is included in Orange Book if information is submitted within 30 days of New Drug Application approval or issuance of patent.
- All Food and Drugs Administration approved drug products are listed in the Orange Book along with their therapeutic equivalence codes.
- A balance is required between reward for new drug innovation and access to drugs through generic competition.
- Abbreviated New Drug Application is a duplicate of a previously approved drug that relies on Food and Drugs Administration's finding that the reference listed drug is safe and effective and is filed under section 505(j).

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- Abbreviated New Drug Application can be filed with patent certifications under Paragraph I, II, III or IV.
- Abbreviated New Drug Application with Para IV certification. A certification that a listed patent is invalid, unenforceable or not infringed.
- Market exclusivity can be based on Patent or Food and Drugs Administration approval. Periods of marketing exclusivity and patent terms may or may not run concurrently.
- Food and Drugs Administration approval based exclusivity includes New Chemical Entity clinical data exclusivity, orphan drug market exclusivity, paediatric exclusivity, clinical trials data exclusivity for new indications or new dosage form of old drug.
- Generic drug products need to be compared to Reference Listed Drug to demonstrate therapeutic equivalence and pharmaceutical equivalence.
- Biowaiver is not applicable for all drug products. But where applicable (e.g. Biopharmaceutical Classification System, Class I drugs) comparative in vitro dissolution needs to be demonstrated.

The seminar was anchored by Ms. Kavita R. Pandey, Assistant Professor, Kamla Nehru College of Pharmacy, Butibori, Nagpur and the vote of thanks proposed by Ms. Seema Wakodkar, Assistant Professor, Kamla Nehru College of Pharmacy, Butibori, Nagpur. There was an overwhelming response to attend the seminar and 55 delegates registered for the conference. Mrs. Suhasine G. Wanjari, President, Amar Sewa Mandla, Nagpur and Adv. Abhijit G. Wanjari, Secretary, Amar Sewa Mandal, Nagpur congratulated Dr. S. N. Umathe, the Convenor and Mr. Mangesh D. Godbole, the Organizing Secretary and all teaching and non-teaching staff for the grand success of the programme.

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