Comparative Biosciences Inc.

CBI News

The Reliable Resource for the Biomedical Community

April 2012

CBI introduces some new capabilities - check out our website!

New capabilities:

CBI introduces some new capabilities-checkout our website! CBI is conducting toxicology, pharmacokinetics and efficacy studies in the area of ear and otic indications, including infections, antibiotics, tympanic rupture treatment, battlefield hearing loss. We offer complete histology and assessment of the ear, including hair cell counting and cytocochleograms, as well as ABR during in life.

Recent publications-CBI was acknowledged as conducting the pathology for:
Evaluation of Hind Limb Muscle Volume Using Three Dimensional Ultrasonography following Peripheral Nerve Injury in Rats : Erika Troy, Subhash Saha, Meaghan Skelly, Anindita Ganguly, Jennifer Iaci, Anthony Caggiano, Tom J. Parry (Accorda Pharma, Hawthorne, NY)

For more information, contact Mike Zamora
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FDA New Guidance on Biosimilars

The FDA has proposed three new guidance documents on biosimilar product development. The comment period is open until April 16. "Biosimilar" is to biologics what "bioequivalent" is to small molecules, meaning that the intent is to create an abbreviated approval pathway for biologics that is analogous to the Abbreviated NDA route for generic drugs. Such a pathway was authorized by Congress as part of the Patient Protection and Affordable Care Act of 2010; the relevant portion is referred to as the Biologics Price Competition and Innovation Act of 2009 (BPCI). For the innovating company, the Act provides a 12-year data exclusivity period, meaning that a biosimilar application cannot reference the innovator's data until 12 years after the initial approval. The guidances include scientific considerations, quality considerations, and Q&A.

Concerning scientific considerations, the FDA encourages sponsors to take a stepwise approach, beginning with laboratory experiments to demonstrate structural and functional similarity to the reference product, progressing to animal data, and finally to clinical PK/PD and immunogenicity studies. In general, sponsors must conduct animal toxicology studies or justify not conducting them, for example if there is no relevant animal model. We believe that well considered animal studies will prove as important to developing biosimilars as they are to any other biotech product. Comparative Biosciences stands ready to apply our extensive knowledge of biotech development to your innovative and biosimilar projects.

Phoenix Micron Retinal Scanner and Laser

CBI now has a Phoenix Micron Retinal Scanner to facilitate detailed retinal angiographic examination of mouse, rat and rabbit retinas as well at for inducing CNV lesions with the laser. OCT and ERGs are coming soon.

About CBI

Join Our Mailing List!

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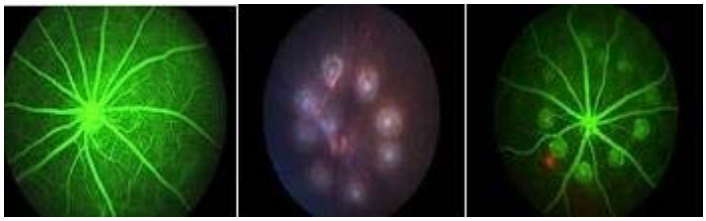

For information on pre-clinical ophthalmic pharmacokinetics, efficacy modeling and toxicology services offered at CBI, contact Mike Zamora, Business Development Manager

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Forward email