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US FDA to reduce backlog of generic drug applications, increase inspections

With US Food and Drug Administration (FDA) planning to work towards reducing the backlog of generic drug applications under the Generic Drug User Fee Act (GDUFA), Indian pharmaceutical companies have however cited challenges like approval time for abbreviated new drug applications (ANDAs)– the applications filed for generic drugs and heightened inspection activities, as GDUFA requires stepping up number of foreign inspections.

Source: http://pharmabiz.com/ArticleDetails.aspx?aid=80484&sid=1

India, Denmark to begin joint research projects in human health science biotechnology

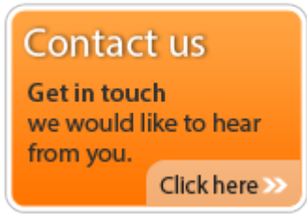
India and Denmark will soon embark on joint research projects in the area of human health science biotechnology to strengthen and intensify the research effort within the area of human health science biotechnology and to integrate the specific competencies of the Indo-Danish research groups involved.

Source: http://www.pharmabiz.com/NewsDetails.aspx?aid=80695&sid=1

US FDA listens to Indian concerns on regulatory scrutiny, but maintains rules are same for all countries

US Food and Drug Administration (FDA) has assured India to help Indian companies to 'identify operational problems' and 'initiate measures for self-correction', but claimed that it adopted uniform standards for all the countries, even as the industry captains raised the concerns about the increased regulatory scrutiny with the visiting US FDA commissioner Dr Margaret Hamburg.

Source: http://www.pharmabiz.com/PrintArticle.aspx?aid=80363&sid=1



About us: Lotus Labs is a Clinical Research Organization working towards widening the frontiers of Medicine through services of the highest Quality that conform to International Standards, combining speed, accuracy and reliability and aims to be the most admired Clinical Research Organization from India