



Press Release

Granules India receives US FDA approval for Ibuprofen Tablets

Hyderabad, September 16, 2015: Granules India Ltd., today announced that the US FDA has approved its Abbreviated New Drug Applications (ANDA) for Ibuprofen Tablets USP, 400 mg, 600 mg, and 800 mg.

“It’s my pleasure to state that USFDA completed the review of Ibuprofen ANDA filed by us and has given its final approval. It will further strengthen our base business and enable us to increase our product offering to our customers in USA.” said Mr. C Krishna Prasad, Chairman & Managing Director of Granules India.

About Granules India Ltd.

(BSE: 532482, NSE: GRANULES)

Granules is a fast growing pharmaceutical manufacturing company with world class facilities and is committed to manufacturing excellence, quality and customer service. The Company produces Finished Dosages (FDs), Pharmaceutical Formulation Intermediates (PFIs) and Active Pharmaceutical Ingredients (APIs) for quality conscious customers in the regulated and semi-regulated markets. Granules support customers with unique value, extensive product range, proactive solutions and a global network of associates. The Company’s global presence extends to over 300 customers in 60 countries through offices in India, U.S., U.K., China and Colombia. Granules offer all three components of the pharmaceutical value chain which gives the customers flexibility and choice.

Granules has the largest PFI facility in the world with an industry leading 6 ton batch size. The Company has its own ANDAs and dossiers which enable customers to quickly enter a market instead of filing their own applications. Granules has a highly skilled regulatory affairs department that can offer customers support and can help them navigate through regulatory issues.

Granules has strengthened its advantages through its Operational Excellence (OE) department which looks at every step of the manufacturing process in order to gain efficiencies and has also implemented systems that have standardized quality and reduced variation. The Company’s OE program is regularly cited by MNCs as a “best in class” program and is the comparative advantage that lets Granules provide world-class quality products at a lower cost than its competitors. The adoption of the OE philosophy by Granules has earned it several recognitions including The Economic Times Manufacturing Excellence Awards 2011.

Caution Statement:

Certain statements made above may be “forward looking statements” within the meaning of applicable laws and regulations.

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