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We particularly appreciate Kendle's swiftness to handle FDA issues and their intimate knowledge of organizing regulatory facts.

*General Manager of Regulatory Affairs
Sun Pharmaceutical Industries Ltd.*

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Preview Kendle's capabilities

- Strategic regulatory advice for registration of products containing well-established substances and registration of generic products
- Writing, assembly, publication and delivery of submission dossiers to regulatory agencies
- Quality relationships with regulatory agencies worldwide
- Experts located across the world

Working hand-in-hand for timely submissions

Kendle has provided ongoing regulatory advice to Aurobindo Pharma Ltd. in Hyderabad, India, for nearly five years. The company manufactures generic pharmaceuticals and Active Pharmaceutical Ingredients and we're often called upon to assist it with ANDA submissions to the FDA. When up against an FDA deadline, Aurobindo knows it can count on us to submit a dossier on time. With Kendle's close proximity to the FDA Headquarters, Aurobindo can send files electronically to Kendle, allowing us to print, compile and check the application before hand delivering it to the FDA. A copy of the stamped receipt is then returned to Aurobindo, ensuring peace of mind. On one occasion, Aurobindo sent files to us at 4 p.m., and we were able to submit the application the same day.

We know the best way to register your product

The registration of products containing established drug substances and previously-approved (generic) drug products presents unique challenges for regulatory departments worldwide. Not only are there different systems for the registration of true generics (look-alike) compared with products containing well-established, off-patent substances, both of these systems vary according to the specific requirements of regulatory agencies around the world.

In the United States, submission requirements differ for Abbreviated New Drug Application (ANDA) and 505(b)(2) submissions. In addition, applicants outside the U.S. require a U.S. agent to represent them and correspond with the U.S. Food and Drug Administration (FDA) on their behalf. This requires staying in contact with the FDA for any deficiencies in the application that may occur during the review process and ensuring that responses are provided.

In Europe, there are specific procedures for generic products as well as Article 10(3) hybrid and literature-based applications for well-established substances. There is also a new process for the registration of biosimilar products. The guidelines and processes for this procedure are relatively new and there are numerous challenges in the registration of these products. Furthermore, any application made in the European Union has to take into account the reference product and the preferred regulatory procedure.



The Kendle difference

The regulatory process for the registration of established substances can be daunting, and many companies need guidance and assistance in assembling and submitting global applications. With experts located in all the major regions of the world, Kendle is strategically placed to help customers navigate through the complexities of registering established substances with new formulations or new indications.

We're able to conduct quality communications with regulatory authorities, and our close proximity to the FDA in the United States further expedites the processing of applications. Here we're experienced in registering true generics through the 505(j) ANDA process, and the registration of off-patent products through the 505(b)(2) process.



Being a generic company, the business is dynamic and we need to react quickly. Having a single point of contact at Kendle allows us to tackle challenging situations and timelines swiftly.

*Regulatory Affairs Team Leader
Sandoz Pty Ltd.*



In the EU we have close working relationships with many regulatory agencies and have assisted customers with numerous applications for both generic and hybrid submissions. We can guide you in your choice of the most appropriate procedure, reference product and, where applicable, in your choice of Reference Member State. We also have extensive knowledge of the requirements for biosimilars or follow-on biologic proteins, and can help generic companies recognize the specific challenges that may arise when developing such products.

Kendle has experience in the Asia/Pacific region and has managed entire portfolios of generic products for companies based in Australia and international companies looking to enter the Australian market. We can prepare justifications for the common occurrence of bioequivalence studies that don't meet the very specific Australian requirements, and can efficiently coordinate

and manage the Australian requirements for Good Manufacturing Practice clearance for overseas manufacturers. We also can advise on the requirements for Chemistry, Manufacturing and Controls information in this region, which often exceed those of the International Conference on Harmonization (ICH) and therefore may not be considered by international generic companies looking to utilize a harmonized dossier worldwide.

We're able to serve as an agent in the United States, Latin America, Canada and Australia, where it is necessary to have a local agent. We also can help to establish a local presence in the EU.

Our associates will work with you to design a strategy for pursuing the various routes of registration for small molecules and biological products. We have the technical expertise to write all portions of the dossier and we efficiently manage the assembly, publication and delivery to the regulatory agencies.

Because we have an in-depth understanding of what is needed to register a product with minimal concerns raised by the regulatory agencies, we can provide a fast, streamlined submissions service with full publishing capability for paper and electronic submissions, including electronic Common Technical Documents (eCTDs). Ultimately, you can be reassured your time to commercialization will be the shortest possible and your revenue maximized.

For more information

about Kendle's capabilities in the regulatory submission of established drug substances, please contact us at info@kendle.com or at one of the telephone numbers listed below:

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