



Sawai Pharmaceutical Announces Paragraph IV ANDA Filing for Dimethyl Fumarate Delayed-Release Capsules

Osaka, Japan - June 12, 2017 - - [Sawai Pharmaceutical Co. Ltd.](http://www.sawai.co.jp/en/) (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) today announced that through its subsidiary Sawai USA, Inc. (State of incorporation: Delaware) the United States Food and Drug Administration (FDA) has accepted for review its Paragraph IV Abbreviated New Drug Application (ANDA) filing for Dimethyl Fumarate Delayed-Release Capsules, 120mg and 240mg, a multiple sclerosis drug.

The product is the generic equivalent to Biogen Inc.'s Tecfidera® (dimethyl fumarate), indicated to treat patients with relapsing forms of multiple sclerosis. This is Sawai's third Paragraph IV ANDA filing, following Pitavastatin Tablets and Mirabegron Extended-Release Tablets. Sawai recently completed its acquisition of US-based Upsher-Smith Laboratories and will continue accelerating developments for the United States market to drive future growth.

There will be little effect from this acceptance on Sawai's consolidated business forecast for the fiscal year ending March 31, 2018. Sawai will announce any material effect on business results if applicable.

About Sawai

Sawai Pharmaceutical Co., Ltd. was founded in 1929 by Hanpei and Noyo Sawai as Sawai Pharmacy in Osaka, Japan. The pharmacy was rare in this era and contributed to the health of the local residents by selling drugs. After experiencing a shortage of medicines during the periods before, during and after the Second World War, in order to respond to social needs, Sawai Pharmaceutical Co., Ltd., began the mass manufacture of pharmaceuticals. In 1965, the company moved into the manufacture of ethical pharmaceuticals, and subsequently grew into a leading company in the generic pharmaceutical industry. Based on its corporate philosophy "It's always 'Patients First'", since 1997 Sawai has been working on improving the recognition of generic drugs through an aggressive marketing campaign. Sawai focuses on the manufacturing and sales, export and import of generic pharmaceutical products. Sawai has a line-up of around 690 ethical pharmaceuticals, such as cardiovascular drugs, antihyperlipidemic agents, diabetes drugs, anticancer drugs, and OTC drugs. With factories throughout Japan, Sawai is the number one provider of generics to the Japanese market. It listed on the First Section of the Tokyo Stock Exchange in 2003 and trades under the 4555 code. For further information please visit:

<http://www.sawai.co.jp/en/>

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