

# Jouhou Koukai

The information disclosure company

## Jouhou Koukai Announces Japan Master Files Database and JKS Milestone Document

TOKYO, August 8, 2006

Jouhou Koukai Publishing, a JKS business, today announces the simultaneous release of two new additions to the Japan Approvals Database (JAD) and to the JKS Documents collection.

Japan Approvals Database, JAD (ISSN 1550-3399) is the leading English-language database containing key information on over 600 new drugs (pharmaceuticals, biologicals, combination products, contrast media and radiopharmaceuticals) approved in Japan from 1999 to August 2006. Along with the updates of the core JAD Database, starting in Q3/2006 several Extended Databases are scheduled to be added for enhancing the research and information value of JAD. The first of the JAD Extended Databases – JAD Japan Master Files (JAD-MF) contains data for all 1,647 Drug Master Files registered in Japan since the MF system introduction in April 2005, arranged in 12 categories as shown in the screenshot and the list below:

The screenshot shows the 'Japan Drug Master Files' section of the JAD database. It features a search bar and a table with columns for Registration Number, Application Date, Registration Status, Application Status, Application Address, Application Date, Application Name, Registration Number, Application Category, and JKS Number. The table lists several entries, including those for 'Dexamethasone', 'Dexamethasone sodium phosphate', and 'Dexamethasone sodium phosphate injection'. The interface also includes a 'Search' button and a 'Print' button.

Registration Number	Application Date	Registration Status	Application Status	Application Address	Application Date	Application Name	Registration Number	Application Category	JKS Number	Status	Approved
217MF0001	05/10/2005	Submitted	Submitted	Osaka	2005	Dexamethasone		Pharmaceutical	JAD_2_0104	Active	
217MF0002	05/10/2005	Not OK	Not OK	Osaka, Chugoku, Shikoku, Kyushu, Hokkaido, I, Iw, T, Yam.	2005	Dexamethasone sodium phosphate		Pharmaceutical	JAD_2_0104	Active	JAD_2005
217MF0003	05/10/2005	Submitted	Submitted	Osaka	2005	Dexamethasone sodium phosphate		Pharmaceutical	JAD_2_0104	Active	
217MF0004	05/10/2005	Submitted	Submitted	Osaka	2005	Dexamethasone sodium phosphate injection		Pharmaceutical	JAD_2_0104	Active	
217MF0005	05/10/2005	Submitted	Submitted	Osaka	2005	Dexamethasone sodium phosphate injection		Pharmaceutical	JAD_2_0104	Active	
217MF0006	05/10/2005	Submitted	Submitted	Osaka	2005	Dexamethasone sodium phosphate injection		Pharmaceutical	JAD_2_0104	Active	

1. Serial number - the consecutive number of the entries, at present up to 1,647
2. Registration number

3. Registration date
4. Registrant name
5. Alternative name
6. Registrant address
7. Registration item
8. Registration update
9. Registration classification
10. JAD ID Number - JAD Identification Number
11. Status
12. Remarks - such as JAD Entity references (related to manufacturers), etc.

As a companion to the JAD-MF Database published simultaneously is the 82-page JKS Milestone document entitled “Japan Master Files – Overview” – the only and fullest up-to-date English-language description of the basics of the Master File system as implemented in Japan. Translated are excerpts from the Pharmaceutical Affairs Law (PAL) of Japan and key notifications from the Ministry of Health, Labor and Welfare (MHLW). Illustrated representation of the Master Files system is provided, along with the details of registration procedure, the Governmental entities responsible for MF handling and the sample forms used for submission. Research and use of the document is aided by the inclusion of complete references and numerous annotations to help novices to Japanese pharmaceutical regulations.

The newly added JAD Japan Master Files Database and “Japan Master Files – Overview” follow the radical reform of the Japanese pharmaceutical affairs bringing considerable – and previously not permitted opportunities for the foreign pharmaceutical developers, manufacturers and distributors to enter and expand in Japan. As the second largest single country pharma market in the world Japan has always been attractive for overseas entrants in spite of regulatory, trade and linguistics barriers. Dedicated to supporting all new players in the Japanese pharmaceutical market, now by introducing the English-language JAD Japan Master Files Database paired with “Japan Master Files – Overview”, JKS Publishing further facilitates the entry of a wide range of bulk substances and active pharmaceutical ingredients makers from around the world, including the emerging pharma markets of India, China and Korea.

Additional product and subscription information about the new offers is available from the JKS web site:

- for introduction [http://www.jouhoukukai.com/disclosed/jad\\_intro.htm](http://www.jouhoukukai.com/disclosed/jad_intro.htm) -
- pre-subscription orientation -  
[http://www.jouhoukukai.com/members/subscription\\_details.htm](http://www.jouhoukukai.com/members/subscription_details.htm)
- to subscribe -  
[https://id252.securedata.net/jouhoukukai/members/subscription\\_form.htm](https://id252.securedata.net/jouhoukukai/members/subscription_form.htm)
- complete Table of Contents of “Japan Master Files – Overview” is available at  
<http://www.jouhoukukai.com/Merchant2/merchant.mvc?Screen=PROD&Product Code=7 D M001&Category Code=7M>

- JKS Documents Store -  
[http://www.jouhoukukai.com/Merchant2/merchant.mvc?Screen=SFNT&Store\\_Code=JS](http://www.jouhoukukai.com/Merchant2/merchant.mvc?Screen=SFNT&Store_Code=JS)

The JAD Databases are accessible only by the registered subscribers. For browsing all documents and reports published by Jouhou Koukai Publishing, please visit the JKS Documents Store.

### About Jouhou Koukai Services

Jouhou Koukai Services LLC and its business Jouhou Koukai Publishing is a leading provider of English-language information products and services to professional end users in regulatory, scientific, pharma, business and intellectual property (IP) information markets. The Company offers databases, intelligence, and services such as electronic publishing, document delivery and market research with focus on the Japanese life sciences and medicinal products industries primarily to the regulatory, executive, business development, licensing, IP, IT (including e-health), research and medical communication professionals worldwide.

Media contact:

Tel: +81-367-174-195 / [pr\\_jks@jouhoukukai.com](mailto:pr_jks@jouhoukukai.com)

Subscribers inquires: [orders@jouhoukukai.com](mailto:orders@jouhoukukai.com)



Editorial Office

Shinagawa Intercity Tower A, 28F, Konan 2-15-1

Minato-ku, Tokyo 108-6028, Japan

International Tel: +81-367-174-195

International Fax: +81-367-174-141

Email: [jouhoukukai@jouhoukukai.com](mailto:jouhoukukai@jouhoukukai.com)

Web: [www.jouhoukukai.com](http://www.jouhoukukai.com)

[www.ehealth-japan.com](http://www.ehealth-japan.com)

[www.licenscape.com](http://www.licenscape.com)

This Press Release is available also online at:

<http://www.jouhoukukai.com/company/newsletters/allnewsletters.htm>