

WHAT'S NEW

NEW HEALTHCARE-RELATED
PRODUCTS, SERVICES, AND
COMPANIES

FDA ANTICOUNTERFEITING DRAFT Focuses on Chemical Identifiers

The FDA has issued a draft guidance on the use of inks, pigments, flavors, and other physical-chemical identifiers (PCIDs) by manufacturers of solid oral dosage forms, which include pills and capsules, to make drug products more difficult to duplicate by counterfeiters and to make it easier to identify the genuine version of the drug.

"Drug counterfeiting is a serious public health concern," notes Commissioner of Food and Drugs Margaret Hamburg, M.D. "We look forward to working with industry to help ensure that consumers are not exposed to products containing unknown, ineffective, or harmful ingredients."

A PCID is a substance or combination of substances possessing a unique physical or chemical property used to identify and authenticate a drug product or dosage. In addition to inks, pigments, and flavors, specific chemicals may be used as molecular tags in a PCID. In some cases, the PCID may be easily detected by wholesalers or pharmacists to determine if they have authentic products. In other cases, special analytical instruments may be necessary to identify whether the PCID is present.

In the draft guidance, the FDA anticipates that many of the potential PCID ingredients are already used as food additives, colorants, or other types of inactive ingredients with established safety profiles.

To minimize adverse effects, the draft guidance recommends using the lowest level of PCID that ensures identification of the product. It also recommends that the PCID be a substance with no medicinal effect and placed within the dosage form so that it does not interact with the drug's active ingredient.

Lewin Group Forms COMPARATIVE RESEARCH CENTER

New center provides data and analysis to help set priorities and support fact-based healthcare decisions.

The newly formed Lewin Group Center for Comparative Effectiveness Research has the goal of meeting the growing need for fact-based, comparative effectiveness research (CER) for use by policy-makers, researchers, healthcare providers, and others to improve patient care and optimize resources.

The center has unique capabilities for conducting and supporting CER, combining The Lewin Group's independent analysis of health information technology, evidence-based medicine, healthcare policy, and other issues; affiliate company i3's expertise in clinical trials and study design, drug safety, health economics, and outcomes research; and Ingenix data. Through Ingenix, the center has access to robust longitudinal, de-identified patient data sets, including integrated medical, disability, laboratory results, and pharmacy claims data.

The Lewin Group Center for Comparative Effectiveness Research offers development and manage-



The investment of more than \$1 billion in federal funding to be used for CER through the American Recovery and Reinvestment Act of 2009 underscores the important role this kind of research plays in setting priorities to improve access to care, care outcomes, and resource use across the nation, says Lisa Chimento.



In consolidating access to our CER expertise, capacity, and capabilities from across Ingenix via this center, we are well-equipped to respond to market demands for CER as a better foundation for healthcare policy and decision making, says Clifford Goodman.

ment of data sets and registries; data analysis, including linked data sets and electronic health records; tools for analysis of longitudinal health outcomes for treatment effectiveness and drug safety; services to conduct and manage institutional review board-approved comparative trials; and CER technical assistance, CER knowledge transfer, and consulting on CER methods and policies.

Clifford Goodman, VP of The Lewin Group, is acting as interim director of the center and will continue as an adviser to the center once a permanent director has been appointed. In addition, Tina Brown-Stevenson, senior VP, healthcare innovation and information at Ingenix, and William Crown, Ph.D., president of i3's Innovus health economics and outcomes research business, serve as advisers to the center.

"As the U.S. government and healthcare industry work together to transform healthcare delivery, CER is fundamental to making fact-based decisions to improve patient outcomes with efficient use of healthcare resources," says Lisa Chimento, Lewin senior VP.

Scientific Collaboration Aims to IMPROVE DRUG SAFETY

The Hamner Institutes for Health Sciences and the University of North Carolina at Chapel Hill have announced the official launch of The Institute for Drug Safety Sciences. The nonprofit institute is led by Paul Watkins, M.D., an expert in drug-induced liver injury and the Verne S. Caviness Distinguished Professor of Medicine at UNC-Chapel Hill. As founding director for the Institute, Dr. Watkins has already assembled a core group of internal scientists and academic partners to develop new global drug safety initiatives in collaboration with the bio/pharmaceutical industry, the National Institutes of Health (NIH), and the FDA.

The Institute's initial focus is developing new computational models and in vitro assays, starting first with evaluating liver toxicity and expanding into cardiovascular and kidney drug side effects.



The Institute for Drug Safety Sciences is dedicated to using the latest scientific techniques to understand, predict, and avoid adverse events from drugs to speed delivery of important new drugs to the patients who need them, says Dr. Paul Watkins.

"It now takes more than a decade and \$1 billion from the time a new drug is discovered to the time it is approved by the FDA," Dr. Watkins says. "Increasingly, these costs and delays relate to proving a drug is safe well after it has been shown to be beneficial."

imc² Launches **HEALTH AND WELLNESS AGENCY**

imc² has established imc² Health & Wellness, an agency focused on the marketing and business challenges facing brands in the pharmaceutical, biotech, device, medical education, healthcare, and wellness industries.

imc² formalized its healthcare practice in response to the industry's challenging marketplace concerning healthcare reform, the evolving regulatory environment, and the shift toward fostering deeper relationships with healthcare professionals, consumers, payers, and other audiences. The new agency is led by Hensley Evans, who has been promoted to president, from her previous role as imc²'s senior VP of strategy.

"With the current state of the healthcare industry, we saw an opportunity to leverage our deep



imc² Health & Wellness allows us to better serve our clients, helping them to build more sustainable relationships between their brands and people, says Hensley Evans.

industry expertise to create an agency focused solely on the distinctive marketing needs of the health and wellness space," Ms. Evans says.

The new agency's leadership team also includes Bonnie Sayers, VP, general manager; Karen Carr, VP, strategic growth and innovation; Amber Benson, VP, strategy; Renee McKeon, VP, creative; and Tom Donnelly, VP, Northeast.

ScopeMedical Establishes **U.S. OPERATIONS**

European communications agency ScopeMedical has opened offices in Princeton, N.J., enhancing its ability to provide services to a growing base of clients in the United States, as well as offer U.S.-focused medical communications programs.

"Our mission is to deliver not only the very best quality service, but to innovate around our clients' constantly evolving needs, while ensuring we operate within regulatory boundaries," says Jeremy Williams, CEO of ScopeMedical.

In addition to strategic communication planning, ScopeMedical offers a full range of promotional medical education services, including publications planning, event management, thought leader development, product training, and e-healthcare solutions.



We have operated extensively in Europe for almost 15 years and are now responding to demand from clients to expand our offering to the United States, says Jeremy Williams.

FDA Enhances Speed and Transparency of Actions **TAKEN AGAINST INVESTIGATOR MISCONDUCT**

The FDA has stepped up its efforts to prevent noncompliant investigators and others from participating in new product development. The FDA's procedures for debarment and disqualification have been enhanced to better protect participants in clinical studies and to ensure the safety and effectiveness of medical products.

The revamped debarment and disqualification procedures, which include increased staffing and centralized coordination, ensure that more rapid, transparent, and consistent actions are taken. In the

short time these measures have been in effect, the number of debarment actions has risen considerably and the times for resolving both disqualification and debarment actions have been reduced significantly. The agency has also taken steps to ensure that sponsors have ready access to information about its debarment and disqualification actions. The FDA has already added to its Website a single page where all pending and completed disqualification proceedings can be found and is currently doing the same for debarment proceedings.

TogoRun Opens **WASHINGTON, D.C., OFFICE**

TogoRun has established an office in Washington, D.C., to work with clients to affect legislative, regulatory, and purchasing decisions at both federal and state levels.

The agency tapped Anne Woodbury, a recognized healthcare public affairs and public policy expert, as senior VP and managing director of the new office. Previously, she was a senior VP at Fleishman-Hillard.

"Now, more than ever, clients want keen insights and informed strategies to help them understand and manage the impact of healthcare reform," says TogoRun President Kathy Hyett.

TogoRun's Washington, D.C., team provides clients with a full suite of public affairs and communications services that include stakeholder engagement, social networking, policy analysis and research, public opinion polling, government relations, and digital and traditional media relations.

"We have only begun to taste the change that is unfolding as a result of potential reform to our nation's healthcare policy," Ms. Woodbury observes.



TogoRun not only works with clients to respond to the opportunities and threats, we help them thrive in this new environment, says Anne Woodbury.

Wolters Kluwer Health Offers **FORECASTING SERVICE**



Rather than simply striving to offer more data faster, our approach sifts through the clutter to synthesize what is truly important, says Ben Weintraub.

Wolters Kluwer Health has unveiled inThought, a market research service that offers an array of pharmaceutical forecasting capabilities.

Financial analysts, healthcare suppliers, and drugmakers can now determine where developmental drugs, medical devices, and therapies are

today and where they are likely headed in the future.

inThought is among the first of a new generation of research services that can deliver data, analysis, and forecasting from a single source, a cost-effective approach that helps streamline the market research process.

The service integrates Wolters Kluwer Health's clinical, prescription, managed markets, and patient information with the insight and forecasting abilities of researchers, analysts, and physicians.

"With research headcounts down, there's a fundamental shift in the way analysts and pharmaceutical customers want their research delivered," says Ben Weintraub, director of research, inThought.

AROUND THE GLOBE



- ▶ Global CRO **CHILTERN INTERNATIONAL** has expanded its operations in central and eastern Europe by opening new offices in Brussels and Budapest. Chiltern has appointed Maurizio Passinisi as country manager for Belgium and the Netherlands, and Attila Lorinczi, M.D., has been tapped to lead the Budapest operation.
For more information, visit chiltern.com.
- ▶ **EISAI EUROPE LTD.** has officially opened its new European headquarters campus at Hatfield Business Park in Hertfordshire, England. The new European Knowledge Centre houses the pharma company's European headquarters, research laboratories, clinical development, and Eisai's first European manufacturing facility.
For more information, visit eisai.co.uk.
- ▶ Global health marketing and communications group **EURO RSCG LIFE** has acquired Medicom Group, a London-based medical communications agency, enhancing the group's market access at both the global and European levels. As part of the acquisition, Medicom Group has been renamed Euro RSCG Life Medicom.
For more information, visit eurorscglife.com.
- ▶ **ICON PLC.**, a global provider of outsourced development services to the pharmaceutical, biotechnology, and medical-device industries, has moved its Singapore central laboratory to a new, larger facility. The expansion enables Icon Central Laboratory to expand its test menu offerings in the region to include increased esoteric testing as well as flow cytometry, molecular diagnostics, and biomarkers, complementing the services of Icon's other wholly owned central laboratories in Europe, India, and the United States.
For more information, visit icolabs.com.
- ▶ Pharmaceutical services company **I3** has created a separate operating region and opened a new office in Tokyo as part of an expansion of its operations in Japan. The expansion in Japan builds on its experience with customers in the Asia-Pacific region, gained with its 2006 acquisition of Singapore-based Pacific Pharma Partners Pte.
For more information, visit i3global.com.
- ▶ **MDS PHARMA SERVICES**, a business unit of MDS Inc., has initiated a renovation and expansion of its discovery pharmacology operation in Taiwan to serve the growing global demand for work performed in Asia. The renovation and expansion, scheduled to be completed in 2010, is aligned with the new MDS Pharma Services strategic focus on early-stage operations — discovery through Phase IIa proof-of-concept services — and its commitment to serve clients in an important emerging market.
For more information, visit mdsps.com.
- ▶ **NEW MOMENTUM**, a provider of anticounterfeiting and channel integrity software, has established sales and management operations in China in response to the demand for the company's software solutions in this region. The country manager, Jacky Zhang, is located in Beijing.
For more information, visit newmo.com.
- ▶ Global CRO **PRA INTERNATIONAL** has established an office in South Korea, complementing the company's extensive network of Asian operations and partnerships. PRA has been providing clinical-trial management services in South Korea since 2005, mainly through local partnerships.
For more information, visit prainternational.com.
- ▶ **QUINTILES** has opened a new office in Accra, Ghana, to improve efficiency and expand capacity to monitor the growing number of clinical studies being conducted in western sub-Saharan Africa. Based at the University of Ghana's Noguchi Memorial Institute for Medical Research, the new Quintiles office immediately facilitates monitoring of a large malaria vaccine study now under way.
For more information, visit quintiles.com.

Follow up

THE FDA is the federal agency responsible for ensuring the safety and accurate representation of foods, cosmetics, human and veterinary drugs, biological products, and medical devices sold in the United States. For more information, visit fda.gov.

THE HAMNER INSTITUTES FOR HEALTH SCIENCES is a nonprofit research organization. For more information, visit thehamner.org.

IMC² HEALTH & WELLNESS is an imc² agency specializing in marketing for clients

in the healthcare and wellness industries. For more information, visit imc2healthandwellness.com.

THE LEWIN GROUP is a healthcare policy and management consulting firm. For more information, visit lewin.com.

SCOPEMEDICAL is a provider of medical education and marketing services to the pharmaceutical industry. For more information, visit scopemedical.com.

TOGORUN, part of Omnicom Group Inc.'s Diversified Agency Services (DAS) network, is a

global healthcare communications agency in healthcare, pharmaceutical, and consumer wellness public relations and public affairs. For more information, visit togorun.net.

WOLTERS KLUWER HEALTH, a division of Wolters Kluwer, provides information and business intelligence for students, professionals, and institutions in medicine, nursing, allied health, pharmacy, and the pharmaceutical industry. For more information, visit wkhealth.com.

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