FDA ANTICOUNTERFEITING DRAFT GUIDANCE

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The FDA has issued a draft guidance on the use of inks, pigments, flavors, and other physical-chemical identifiers (PCIDs) by manufacturers of solid oral dosage forms, which include pills and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 the 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In the draft guidance, the FDA anticipates that many of the potential PCID ingredients are already used as food additives, colorants, or other types of inactive ingredients with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.

The draft guidance recommends using the lowest level of PCID that ensures identification of the product.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.

inVentiv Renames PROFESSIONAL DEVELOPMENT BUSINESS

Preceptiv Learning Solutions provides life-sciences clients with specialty training and education services.

Our new name supports our enhanced offering and ability to build our clients' confidence in the skills and competence of their teams, says Bryan Horveath.

As the healthcare selling environment grows increasingly complex, the importance of effective learning and development programs for pharmaceutical sales teams has never been greater, says Peter Marchesini.

Ventiv Professional Development Group, an inVentiv Health company, has rebranded under the name Preceptiv Learning Solutions following the acquisition and integration of specialty training and education businesses Asert and DialogCoach.

Drawn from the word "preceptor," meaning tutor or teacher, the Preceptiv name reflects the company's role as a leader in helping clients achieve their training goals. Fellow inVentiv firm Y Brand has designed the company's new logo, which depicts three interlocking infinity symbols forming the triangular delta symbol indicative of change. This represents the company's dedication to driving transformation in its clients' organizations.

"Bringing Asert and DialogCoach into the organization gave us an opportunity to refocus on building a suite of best-in-class learning solutions that includes creative instructional design, customized and innovative learning, oncology therapeutic expertise, and leadership development solutions," explains Bryan Horveath, senior VP and managing director of Preceptiv Learning Solutions.

"Preceptiv Learning Solutions, backed by the full resources of inVentiv Health, is positioned to drive sales success by developing training programs that are customized to meet the challenges facing today's healthcare companies," adds Peter Marchesini, chief learning officer of inVentiv Health.

In other moves, inVentiv Health has established inVentiv Japan, a Tokyo-based operation that provides outsourced commercialization services to healthcare clients in the Japanese market through the company's Selling Solutions division. In addition to its Selling Solutions offering, inVentiv Health also has communications capabilities in Japan through an affiliate relationship with Ad-comm Group.

inVentiv's sales operation in Japan is led by Dan Feldman, who joins inVentiv from Japan-based Merck-Banyu, where he served as VP of sales.

"Not only have many top-selling U.S. pharmaceutical products not yet launched in Japan, but a growing number of pharmaceutical companies in Japan are looking to increase the flexibility of their workforce," says Terry Herring, president and chief operating officer of inVentiv Health.

"Establishing inVentiv Japan will enable us to fulfill our clients' needs, while also supporting inVentiv's growth as a global healthcare leader," says inVentiv CEO Blane Walter.

PCE Partners with ACU on CONTINUING EDUCATION FOR NPS, PAS

Practicing Clinicians Exchange (PCE) has formed a partnership with the Association of Clinicians for the Underserved (ACU) to provide continuing education programs to nurse practitioners (NPs) and physician assistants (PAs). The ACU educates clinicians who care for patients with limited health literacy and other vulnerable populations. PCE provides customized continuing education for NPs and PAs.

The collaboration between PCE and ACU provides these practitioners with the necessary education related to the numerous challenges they face in delivering optimal healthcare to patients who have limited English proficiency or who may not have the means to pay for medications they need.

"Low literacy individuals can have difficulty successfully negotiating the healthcare system," says ACU President Peter Sherman, M.D. "The problem is multifaceted, requiring comprehensive, multipronged approaches. Health literacy skills need to be infused into medical curricula and continuing education for all clinicians."

"The partnership between PCE and ACU will better prepare clinicians to develop preventive and management strategies that will improve healthcare outcomes for chronic diseases," adds Bradley Mock of PCE.

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Gullapalli Launches **PATIENT-CENTERED CME OFFERING**

Gullapalli & Associates' recently established Patient Centered CME (PCCME) helps empower patients and aids healthcare providers in improving health outcomes.

Dora Ochsenbein has joined Gullapalli as manager of educational planning. Ms. Ochsenbein previously served as director of the Leukemia & Lymphoma Society.

Patients play a vital role in healthcare today and can play an even greater role with the right tools and opportunities, says Dr. Venkat Gullapalli.

Dora Ochsenbein is manager of educational planning responsible for developing, implementing and managing programs.

Through PCCME, patients and medical professionals become active collaborators in making clinical decisions, and patients are given the tools and support to take responsibility for their own self-care and monitoring. Patient-centered care also ensures that transitions between providers, departments, and healthcare settings are efficiently coordinated, reducing unneeded and unwanted services while increasing patient satisfaction and adherence and persistence.

"The goal of the new PCCME service is to work with collaborative partners to facilitate the design and development of med ed curricula that allow healthcare providers to gain an understanding of patient needs and preferences and apply those deeper insights in systematic ways to reap the full benefits of patient-centered care," observes CEO Venkat Gullapalli, M.D.

GxP Consulting Introduces **REGULATORY COMPLIANCE SERVICE**

GxP Consulting has added an extended regulatory compliance and validation project management service to its portfolio, ensuring that companies have the necessary skills, training, and support needed to deliver projects efficiently and effectively while complying with global regulatory requirements.

With a team led by Tom Dine, regulatory compliance and project management principal consultant, the service integrates the requirements of the entire drug development life cycle.

"We are positioned to be able to provide our clients with knowledge and experience that combines the discipline of project management with a comprehensive technical and regulatory compliance understanding of the development, approval, manufacture, packaging, storage, and distribution of pharmaceutical, biopharmaceutical, medical device, veterinary, and homeopathic products," Mr. Dine says.

Industry Veterans Form **SCIENCE BRANDING COMMUNICATIONS**

Science Branding Communications, a new agency founded by veteran pharma professionals Bill Hahn and Edward Perper, M.D., addresses the current challenges faced by pharma, including increasingly complex compounds, highly competitive market conditions, tight regulatory oversight, and shrinking commercialization budgets. Science Branding brings together a team of physicians, scientists, marketers, compliance experts, and creative directors with the experience and expertise to simplify complex science; develop a science foundation; differentiate the new compound; and produce compelling and compliant disease-state educational programs.

Co-Founder Bill Hahn serves as President of Science Branding Communications.

Co-founder Dr. Edward Perper serves as CEO of the new company.

Mr. Hahn, co-founder and president, brings four decades of pharmaceutical sales and marketing experience to Science Branding, most recently as a founding partner of Shaw Science Partners. Dr. Perper, co-founder and CEO of Science Branding, has been involved in the digital medical education field for more than 20 years. A graduate of Harvard Medical School, he trained in cardiovascular medicine at Stanford University Medical Center, and most recently served as a strategic scientist and medical director with Shaw Science Partners.

SEE DIGITAL EDITION FOR BONUS CONTENT WWW.PHARMAVOICE.COM

Follow up

ASSOCIATION OF CLINICIANS FOR THE UNDERSERVED (ACU) is a nonprofit organization of clinicians, advocates, and healthcare organizations with the mission to improve the health of underserved populations and enhance the development and support of healthcare clinicians. For more information, visit cealliance.org.

GULLAPALLI & ASSOCIATES is a firm of strategic healthcare consultants specializing in collaborative medical education initiatives. For more information, visit gullapalliandassoc.com.

GXP CONSULTING provides high-value, results-focused regulatory compliance services to the highly regulated pharmaceutical and biopharmaceutical industries. For more information, visit gxpeu.com.

INVENTIV HEALTH INC. delivers customized clinical, sales, marketing, and communications solutions. For more information, visit inventivhealth.com.

PRACTICING CLINICIANS EXCHANGE (PCE) provides continuing education focused specifically on the needs of NPs and PAs. For more information, visit practicingclinicians.com.

SCIENCE BRANDING COMMUNICATIONS builds custom programs for life-sciences companies based on their educational objectives and target-audience preferences. For more information, visit sciencebranding.com.

THE U.S. FOOD AND DRUG ADMINISTRATION (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.

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FDA Issues Final Rules to Help
PATIENTS GAIN ACCESS TO INVESTIGATIONAL DRUGS

The U.S. Food and Drug Administration (FDA) has published two rules that seek to clarify the methods available to seriously ill patients who are interested in gaining access to investigational drugs and biologics, but are ineligible to participate in a clinical trial and lack other satisfactory treatment options.

The first rule, Expanded Access to Investigational Drugs for Treatment Use, makes investigational drugs more widely available to patients by clarifying procedures and standards. The second rule, Charging for Investigational Drugs under an Investigational New Drug Application, clarifies the specific circumstances and the types of costs for which a manufacturer can charge patients for an investigational drug when used either as part of a clinical trial or outside the scope of a trial.

To support the effort to help these patients, the agency also is launching a new Website where patients and their healthcare professionals can learn about options for investigational drugs. These options are to be treated with a drug that has been approved by FDA; to be given an investigational drug as part of a clinical trial; or to obtain access to an investigational drug outside of a clinical trial.

"With these initiatives, patients will have the information they need to help them decide whether to seek investigational products," says Margaret Hamburg, M.D., commissioner of food and drugs. "For patients seeking expanded access to investigational drugs and biologics, the new rules make the process easier to understand."

"The final rules balance access to promising new therapies against the need to protect patient safety and seek to ensure that expanded access does not discourage participation in clinical trials or otherwise interfere with the drug development process," adds Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

ON THE SHELVES

- **DRUG SPELLER: 2009** by Dictionary Jumpstart is a reference book that offers the correct spelling for more than 10,000 commonly used drugs, including prescription, brand name, generic, experimental, and discontinued pharmaceuticals. Intended to launch an ongoing annual series, the book organizes drug names in alphabetical order, as well as categorizing information into 36 medical specialties, including cardiology, fertility, and diabetes.

  For more information, visit dictionaryjumpstart.com.

- **THE GRC ASSESSMENT TOOLS GUIDE**, commonly known as the Burgundy Book, is now available for use by member organizations of the Open Compliance & Ethics Group (OCEG) Enterprise Solution. The Burgundy Book provides a common set of agreed-upon procedures and criteria for assessing GRC processes, including compliance programs, as well as workbooks and report templates.

  For more information, visit oceg.org.

- Thomson Reuters has announced the availability of the 2009 edition of the **CMR INTERNATIONAL PHARMACEUTICAL R&D FACTBOOK**, its compendium of pharmaceutical research and development statistics. This year's Factbook offers extended content, including patent information and emerging trends in worldwide pharmaceutical R&D.

  For more information, visit thomsonreuters.com.

- Wolters Kluwer Health has made enhancements to its online drug information reference, **FACTS & COMPARISONS ONLINE FOR HEALTH SYSTEMS**. Among the most notable updates are a more intuitive user interface, deeper integrated content, simplified searching, and smarter tools to arm pharmacists and clinicians with evidence-based drug information that drives the best therapeutic decisions in less time.

  For more information, visit wolterskluwerhealth.com.

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