FDA to Propose New Labeling Responsibilities for ANDA Sponsors

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PHARMACEUTICAL DEVELOPMENT GROUP

Subsequent to the passage of Hatch Waxman in 1984, generic sponsors have been required to conform to RLD labeling, including safety related information.

This may all be about to change!

Many of PDG's labeling efforts and recommendations are in wide use today and include:

- Professional Labeling for Prescribers
- Medication Guides
- Patient Labeling
- OTC Drug Facts
- Dear Healthcare Professional Letters
- Promotional Labeling

FDA announced a proposed rule will be issued by the end of September 2013 to provide regulatory requirements for generic sponsors to implement certain safety-related changes in their labeling[1]. According to Forbes[2], once the proposed changes are implemented *"the generic drug makers will run the same risks as the brand-name drug companies. They would face unprecedented liability if their warnings or other label information don't pass muster, and if their products injure consumers."*

How will the proposal impact generic companies?

Generic sponsors may need to analyze the evolving safety profiles of their drug products with unprecedented rigor. This would include analyses of scientific literature, spontaneous adverse event reports, post-marketing databases and epidemiology studies, trending analysis, signal detection efforts, etc.

What types of label changes are involved?

Various safety-related sections of drug labeling may change. The proposed rule will create similar tasks for brand-name and generic sponsors as to post-marketing requirements for label revisions, including submission of CBE labeling supplements.

How can generic drug sponsors learn more about this?

PDG has posted a copy of FDA's announcement to our website: Fed. Reg. July 23, 2013 (Vol. 78 No. 141 44252); Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products (www.pharmdevgroup.com/newrule). Please call or e-mail us and we will help answer your questions. Our contact information is on the back of this page.

How should generic drug sponsors prepare for this?

PDG has long term experience in assessing and integrating evolving safety data and information, and can draft new drug labeling to ensure its ongoing adequacy and currency.

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[1] Fed. Reg. July 23, 2013 (Vol. 78 No. 141 44252) located at www.pharmdevgroup.com/newrule

[2] Generic Drug Makers Will Soon Face The Regulatory Music. Richard Levick, Contributor. July 15, 2013 (http://www.forbes.com/sites/richardlevick/2013/07/15/generic-drug-makers-will-soon-face-the-regulatory-music/ as accessed on August 20, 2013)

How will PDG assist your company?

PDG will conduct a comprehensive assessment of all relevant studies and post-marketing safety databases including safety signal detection. We will assess your labeling to determine if it reflects any/all applicable safety concerns. If needed, PDG will recommend labeling modifications along with suggestions for ANDA implementation and FDA interactions.

With extensive experience in securing FDA approvals, PDG is well versed in strategic product evaluation and labeling consulting.

Why rely upon PDG?

Our service is predicated upon years of successful industry and FDA experiences with both generic and proprietary products. PDG assists FDA regulated firms in the navigation of the U.S. submission, approval and compliance procedures across a variety of dosage forms and the majority of the therapeutic areas. Our expertise spans prescription and non-prescription (OTC) drugs, biologics, medical devices and combination products. PDG has extensive experience with pharmaceutical labeling included with NDAs, ANDAs, and Supplements. Our expertise includes the collection and evaluation of postmarking adverse events, the preparation of updated product labeling, and the dissemination of accurate, complete and timely product related information to healthcare professionals, patients, consumers and FDA. PDG has the necessary experience and expertise to assist generic sponsors in this new era of labeling challenges and responsibilities.

PDG clients are supported by our full time professional staff and consultants including pharmacologists, epidemiologists, toxicologists, clinicians, labeling experts, analytical scientists, regulatory strategists, business development administrators, and others. With extensive combined experience in securing and maintaining FDA approvals, PDG is well versed in strategic product planning and regulatory consulting.

PDG is led by Dr. Cheryl Blume who founded the company in 1999 following a distinguished career in industry that has spanned over 35 years including positions in senior management at Mylan Pharmaceuticals and later Somerset Pharmaceuticals. Throughout her career Dr. Blume has been responsible for INDs, ANDAs and NDAs, including regulatory responsibilities spanning initial submission reports to post-marketing surveillance.

From Pre-IND through Phase IV, PDG believes you should reach the experts you need, when you need them, for any task, from any time zone.

I am Cheryl Blume, Ph. D., President of PDG®. Please contact me directly on my cell at (813) 419-7341 or by eMail via drblume@pharmdevgroup.com. For convenience, scan the QR Code and add my contact information to your cell phone.

PDG®
PHARMACEUTICAL DEVELOPMENT GROUP

13902 North Dale Mabry, Suite 230
Tampa, FL 33618
Ofc: (813) 963-3062 **Fax:** (813) 963-0972

Visit our website at www.pharmdevgroup.com