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Statement by Ralph G. Neas, President and CEO, Generic Pharmaceutical Association, Regarding the FDA Proposed Update to Generic Labeling Regulations

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“Patient safety is the foremost concern for manufacturers of generic medicines, which is why both brand and generic companies comply with federal law and strict FDA labeling rules and regulations. Generic drug companies proactively participate with the FDA in ensuring the timeliness, accuracy, and completeness of drug safety labeling in accordance with current regulatory requirements, to ensure doctors and all healthcare professionals and patients have access to the most up-to-date information.

GPhA has received the FDAs proposed rule and is in the process of careful review with our member companies. With this proposed rule comes the public response period, during which we will fully evaluate the implications of any rule change. We will evaluate this proposed rule both for any elements that could impact patient safety, and for our member company business practices that currently ensure access to affordable, life-saving medicines for millions of Americans.

GPhA is very concerned that multiple versions of critical safety information would lead to unnecessary confusion and uncertainty for prescribers and other healthcare professionals, with harmful consequences for patients. Indeed, the FDA acknowledges in the proposed rule that ‘there may be concerns about temporary differences in safety related labeling for drugs that the FDA has determined to be therapeutically equivalent, especially if multiple ANDA holders submit … labeling changes that differ from each other and from the reference drug.’

Uniform safety information avoids confusing patients, doctors, pharmacists and nurses and assures all healthcare practitioners that they can rely on consistent information to inform their decisions and patient conversations. GPhA intends to address these concerns in its comments to ensure patient safety and confidence in the use of generics is not hindered by the implementation of this proposed change.

Currently, generic manufacturers are required by law to have the exact same label as the brand. Identical labels underscore a critical point — once generic medicines pass through extensive FDA review, they are proven scientifically equal to the brand medicine in terms of safety, efficacy and quality.

The Supreme Court has repeatedly held that generic pharmaceutical manufacturers must duplicate the language on the brand pharmaceutical manufacturer’s labels and cannot make changes to a label without FDA approval. Therefore, the agency’s authority to enact a rule that differs from the federal law is unclear and GPhA will study this aspect as well.

Patients and healthcare practitioners must continue to have access to consistent, transparent information in order to best inform treatment decisions. The generic pharmaceutical industry will continue to work with the FDA and other stakeholders to make sure that any changes to labeling rules and regulations protect patient safety, align with federal laws, and do not hinder patient access to more affordable generic medicines.“

About GPhA

GPhA represents the manufacturers and distributors of finished generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 84 percent of the prescriptions dispensed in the U.S. but consume just 27 percent of the total drug spending, saving the health system nearly $200 billion annually. Additional information is available at www.gphaonline.org. Follow us on twitter: @gpha.