



April 27, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Supplemental Comments of the Healthcare Supply Chain Association (HSCA) regarding Docket FDA-2013-N-0500: RIN 0910-AG94 Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products.

The Healthcare Supply Chain Association (HSCA) appreciates this opportunity to respond to the Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products.^[1] We thank the Food and Drug Administration (FDA) for reopening the comment period following the March 27, 2015, public meeting on labeling changes for approved drugs and biological products, and we appreciate the opportunity to share our thoughts on this important public policy issue.

HSCA is a broad-based trade association representing 14 healthcare supply chain companies and group purchasing organization (GPOs) that include for-profit and not-for-profit corporations, associations, multi-hospital systems and healthcare provider alliances. GPOs provide products and services for both acute and non-acute care healthcare facilities nationwide. Generic drugs—which represent greater than 86 percent of all prescriptions dispensed in the U.S., but only 27 percent of expenditures on prescription drugs—are a significant portion of the GPO portfolio of services provided to healthcare entities such as hospitals and nursing homes.

We share FDA’s concerns regarding implementation and distribution of the most current data and safety information regarding approved drug products. Changes to pharmaceutical product labeling, we believe, must be prompt, uniform and most significantly, accurate. FDA’s long-standing policy states that changes to product labeling should be affected only when “there is reasonable evidence of a causal association with a drug.” We are concerned that the proposed changes would violate FDA’s own stated policy and create an environment that could encourage disparate, inconsistent, and potentially inaccurate information from multiple manufacturers. Such an environment, we maintain, would conflict with the FDA’s goals of promoting and protecting the public health. As you know, the proposed rule would allow generic drugmakers to update their warning labels when they learn of new risks, as brand drug manufacturers now do. Our concern, however, is that manufacturers would unnecessarily be subject to potentially harmful liability for failing to warn patients who may be injured by these drugs.

We support the drugmakers’ request that FDA approve any warning changes before they are added to labels. Not doing so would risk creating a marketplace with multiple warning labels for brand and generic versions of the same drug—potentially confusing patients and threatening public health.

Expedited Agency Review (“EAR”) Process

As an alternative, HSCA supports the Expedited Agency Review (EAR) proposal put forth by the Generic Pharmaceutical Association (GPhA) and the Pharmaceutical Research and Manufacturers of America

^[1]See 78 F.R. No. 219 67985 *et seq.* (November 13, 2013) 21 C.F.R. §201.57(c)(6) (“Notice”).

(PhRMA). EAR satisfies FDA's objective to strengthen and expedite the labeling process, but does so without the potential unintended consequences for patients, providers, taxpayers, payers, and others. Under the EAR process, defined time parameters would be established for FDA to take action on a label change made (1) following FDA's receipt and review of "*new safety information*"^[2] from either an NDA or an ANDA holder; or (2) following review of data received by FDA through the Sentinel System and/or other databases including global sources that suggest a label change. The EAR proposal is in accord with current agency practice as reflected in the various electronic mechanisms FDA has established over the past decade to promptly and accurately notify the public – both healthcare practitioners and consumers – of potential or known adverse effects of approved products.^[3]

In addition, EAR is in accord with FDA's proposed e-labeling technology that will promote the availability of new information expeditiously and in real time. The proposed labeling rule would perpetuate the current paper labeling system that often results in delays for revised new product labeling. EAR reinforces the basic goals set forth in FDA's e-labeling proposal by assuring that all application holders meet their responsibility of reporting safety-related information and making newly-evaluated safety information available to practitioners and the public as soon as possible. Furthermore, the combination of the EAR proposal and e-labeling will not only promote prompt dissemination of new labeling, but also ensure that different labels will not exist in the marketplace at the same time. The public health benefit of e-labeling is clear as it will speed up the availability of accurate, real-time, and consistent labeling of products for pharmacists, physicians, and patients.

HSCA appreciates the opportunity to comment on the FDA's proposed rule on labeling. It is important that any final rule ensures patient and practitioner access to consistent, science-based information to best inform treatment decisions.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Rooney". The signature is fluid and cursive, with a long, sweeping tail on the final letter.

Curtis Rooney
President
Healthcare Supply Chain Association (HSCA)

^[2] "New safety information" has the definition provided in the Guidance for Industry: Safety Labeling Changes – Implementation of Section 505(o)(4) of the FD&C Act, dated July 2013.

^[3] See FDA website, Safety, Subscribe to MedWatch Safety Alerts, available at <http://www.fda.gov/Safety/MedWatch/ucm228488.htm> (permitting subscriptions to the MedWatch E-lists to receive e-mail notifications titled "FDA Updates for Health Professionals," "Consumer Education about Medicine," "Recalls, Market Withdrawals and Safety Alerts," and "Press Releases" to name a few; permitting the public to follow MedWatch via twitter; and to sign-up for MedWatch RSS feeds).