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April 12, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 2006N-0465, Comments Pertaining to Improving Patient Safety by Enhancing the Container Labeling for Parenteral Infusion Drug Products, Notice of Public Meeting and Request for Comments

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments, in addition to its verbal statement presented at the January 11, 2007 public meeting on improving patient safety by enhancing the container labeling for parenteral infusion drug products. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in a variety of health system settings, including inpatient, outpatient, home care and long-term-care settings.

ASHP is pleased that the Food and Drug Administration (FDA) held this public meeting, and commends the agency for recognizing and addressing issues associated with intravenous medication use, and the need to explore how current IV labels should be designed to minimize medication errors. The issues discussed in the workshop directly affect ASHP members who handle large and small volume parenteral infusion drug products, as well as patients who are treated with intravenous therapy. In submitting these comments, the Society wishes to expand on the following topics covered in its verbal comments: Application of human factors principles, use of bar coding, collaboration for risk reduction, and enhancement of FDA guidance and regulatory control.

Application of human factors principles

Labeling and packaging practices for many large and small volume parenteral products exhibit lack of knowledge for established principles for preventing human error, as evidenced by lack of standardization, ambiguous or poorly visible labeling, confusion about the use of color coding, and dependence on practitioners to note subtle details.

For example, healthcare practitioners working in busy practice settings may not note differences in labels that are identical except for a half-dozen or so characters that express a different strength. Similarities of color, design, graphics, and packaging may lead to identifying products by appearance, rather than by label information.

While engineers have historically used principles from cognitive psychology and ergonomics as guidance for design in technology, manufacturing, aviation, and other areas requiring human interface, the use of human factors sciences to prevent medical errors is a more recent development. Design and labeling of medical devices is one of the early applications.

ASHP is pleased that, in the Agency's reauthorization proposal for the Prescription Drug User Fee Act of 1992 (PDUFA), Reauthorization Performance Goals and Procedures, submitted to Congress on March 16, 2007, FDA recognizes the need for a review of proprietary names to reduce medication errors, stating: "To enhance patient safety, FDA will utilize user fees to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names and such factors as unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design."

Additionally, a previous FDA initiative to improve instruction manuals for medical devices (Human Factors Principle for Medical Device Labeling, James R. Callan, John W. Gwyne, Pacific Science & Engineering Group, <http://www.fda.gov/CDRH/dsma/227-a.pdf>) is an example of expert guidance that may be applicable to large and small volume parenteral label design. These principles address methods of visual display that optimize readability and comprehension by the user, including use of color, graphics, placement, and emphasis of important information.

ASHP is aware of FDA current efforts to incorporate human factors concepts in its risk assessments of medical devices. The Society recommends that the FDA continue to explore the utilization of human factors concepts and maximize their use to detect potential for error with medications and their labeling.

Use of bar code scanning technology to prevent errors

ASHP strongly supports the use of bar code scanning technology as one means to accurately identify medications prior to preparation, dispensing, and administration to the patient. ASHP also supports current FDA regulations requiring manufacturers to label all pharmaceutical product packages with bar codes that contain the NDC number for the medication. The Society recommends that the bar codes be required to contain the lot number and expiration date as well.

ASHP strongly advocates that hospitals and health systems adopt bar code scanning technology to prevent patient harm, and recommends the FDA and the pharmaceutical industry ensure that bar codes placed on small and large volume parenterals as well as all other drug products are scannable. A new barcode problem reporting mechanism has now been provided to ASHP membership and data will be shared with FDA, manufacturers, device vendors, as well as members.

Collaboration for risk reduction

ASHP was pleased to see input by manufacturers, practitioners, regulatory and accreditation agencies and patient groups at the January 11 meeting. The Society is also encouraged to see medication safety organizations such as USP and ISMP involved in the program. However, ASHP believes that workable solutions can only be developed by consensus of all the stakeholders. We recommend that any proposed changes to container labeling for parenteral

Department of Health and Human Services
Food and Drug Administration
April 12, 2007
Page Three

infusion drug products requirements should also be evaluated by human factors experts as well as pharmacists, nurses, and physicians who handle these products to ensure the best chance for effective solutions.

More specific guidance and increased regulatory control

ASHP recommends the FDA incorporate relevant findings from user evaluation and human factors science into more specific guidance to industry on packaging and labeling. ASHP further recommends that the Agency exert more regulatory control to change packaging and labeling practices known to cause error or evaluated to be at risk for error.

ASHP reiterates that patient safety is significantly compromised by the poor quality of container labeling for parenteral infusion drug products, and further recommends that these issues receive priority attention from the agency.

ASHP appreciates this opportunity to present its written comments on improving patient safety by enhancing the container labeling for parenteral infusion drug products. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey".

Justine Coffey
Director, Federal Regulatory Affairs