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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0465]

Improving Patient Safety by Enhancing the Container Labeling for Parenteral Infusion Drug Products; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on improving patient safety by enhancing the container labeling for parenteral infusion drug products. This will be a 1-day workshop involving FDA staff and representatives of the United States Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). The purpose of the meeting is to explore how labels on intravenous (IV) drug products could be designed to minimize medication errors. Design issues include placement, style and type of information, the need for standard expression of strength, quantity of information, and use of color on the label.

DATES: The public meeting will be held on January 11, 2007, from 8 a.m. to 4 p.m. Submit written or electronic requests to speak by December 28, 2006. Written or electronic comments to the docket will be accepted until April 12, 2007.

ADDRESSES: The public meeting will be held at the Lister Hill Center Auditorium (the center), National Institutes of Health (NIH) campus, 9000 Rockville Pike, bldg. 38A, Bethesda, MD 20815, 301–496–4441. The center can be reached by Metro using the Medical Center Station on the red line. Parking

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is limited at NIH, so Metro use is recommended. For directions and visitor information, see *http://www.nih.gov/about/visitor/index.htm*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written or electronic requests to speak at the meeting to the information contact. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/cder/meeting/parenteral_labeling.htm*.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research (HFD–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–2380, e-mail: *jean.chung@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Premixed large volume parenterals (LVPs) and small volume parenterals (SVPs) in ready to infuse final dosage forms are designed to deliver premixed drugs (e.g., antibiotics, electrolyte solutions, pain management infusions). Premixed LVPs and SVPs improve standardized drug delivery and can reduce the potential for medication errors by reducing the steps required in IV preparation and the additional quality control checks needed by the pharmacy prior to dispensing and administering the product. Premixed LVPs and SVPs: (1) Provide an end product that is labeled with the ingredients including a product identification code (e.g., bar code), (2) promote a sterile environment, and (3) maintain accurate concentration within a closed system. According to

the USP, "the designation large-volume intravenous solution applies to a single-dose injection that is intended for intravenous use and is packaged in containers labeled as containing more than 100 mL. The designation small-volume injection applies to an injection that is packaged in containers labeled as containing 100 mL or less."

Although premixed LVPs and SVPs can reduce the potential for mixing errors, the labels and labeling of these products, as well as base solutions of LVPs and SVPs without drug, have been documented as contributing to medication errors in both acute care and ambulatory settings, as well as in home care settings. The types of errors reported involve the inability to distinguish different drug products, as well as different strengths of drug products, because the containers look similar and use similar colors for label text. In addition to these visual similarities, manufacturers may label the same drug product with varying units of measure (e.g., micrograms versus milligrams), which has also contributed to error. There is also a large amount of information that is placed on the container label that can not only crowd the label but can distract from the most important information, that is, the proprietary and established names and product strength.Thus, we would like to explore how current IV labels should be designed to minimize medication errors.

II. Scope of the Public Meeting

The public meeting is intended to explore how IV labels could be designed to minimize medication errors. Design issues include placement, style and type of information, the need for standard expression of strength, quantity of information, and use of color on the label.

This 1-day workshop will assemble drug safety experts, patient advocates, government experts, and pharmaceutical and device manufacturers to discuss outstanding regulatory, technological, and resource issues. Other interested constituencies (e.g., patient advocacy and education groups, pharmaceutical sponsors, general public) will have an opportunity to provide input during the question and comment periods. FDA is interested in obtaining public comment and encourages all interested parties to submit requests to speak at the meeting or to submit written or electronic comments to the docket. (See sections III. and IV. of this document.)

The meeting will include an overview of FDA and USP requirements, presentations from the clinical perspective (nurse and pharmacist) and industry perspective, and a series of panel discussions. The following topics will be discussed: Look-alike containers, confusing labels on sterile water containers, container label requirements, and the lack of standardized expression of medication concentration on labels. Questions that will be considered during this public meeting include, but are not limited to, the following:

1. What are the best solutions to differentiate look-alike container labels of premixed LVPs and SVPs containing different medications (among different product lines from the same manufacturer and across different manufacturer product lines)?

2. Would the use of color differentiation on labels prevent medication errors? Can different colors be used on intravenous bags? If not, what are the barriers and possible ways to address them?

3. What information currently required to appear on intravenous container labels can be eliminated or placed elsewhere in order to make room for more

important information such as barcodes, larger font size for drug names, new standard ways to express drug concentration, and product warnings? How can industry make the best use of the limited space on labels? What type of standards for layout and type size would need to be applied to correct for the confusion among the products?

4. How does the lack of standardization in the expression of medication concentrations on labels contribute to error? How can we standardize the expression of drug concentrations on IV drug container labels?

5. How do the similar labels for Sterile Water for Injection, Sterile Water for Irrigation, and Sterile Water for Inhalation lead to medication errors (i.e., deaths in some instances have been reported)? How can the label for sterile water be improved to minimize the risk of confusing the different routes of administration?

6. What strategies are there to prevent inadvertent administration of solutions not intended for parenteral IV use?

7. What are the regulatory, technological, and resource (cost) barriers that would need to be eliminated to correct the challenges identified today, if any? What are the practical resolutions to address these challenges?

III. Registration, Requests to Speak, Agenda, and Presentations

No registration is required to attend the meeting. Seating will be on a first-come, first-served basis. If you need special accommodations due to a disability, please inform the contact person (see **FOR FURTHER INFORMATION CONTACT**).

Interested persons may request to speak at the meeting (see **FOR FURTHER INFORMATION CONTACT**). Statements from the public will be scheduled between 2:45 p.m. and 3:45 p.m., and the time allotted for each speaker will be limited. Requests to speak at the meeting should include: (1) The specific topic or issue

to be addressed, (2) a brief summary of remarks, and (3) the participant's name, address, telephone number, and e-mail.

The agenda for the public meeting will be available on FDA's Center for Drug Evaluation and Research (CDER) Web site at: *http://www.fda.gov/cder/meeting/parenteral_labeling.htm*. After the meeting, the agenda, presentations, and transcript will be placed on file in the Division of Dockets Management under the docket number found in the heading of this document and on CDER's Web site identified in the previous sentence.

IV. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics discussed in this document (see **DATES**). Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Copies of the transcript may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 20 working days after the meeting at a cost of 10 cents per page or on compact disc at a cost of $14.25 each. You may also examine the transcript at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/20/06
November 20, 2006.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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